IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-95 (GMS)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

DECLARATION OF ANDREW J. DANFORD

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Kevin Prussia
Andrew J. Danford
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(627) 526-6000

Robert J. Gunther Jr.
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

MORRIS NICHOLS ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Genentech, Inc., City of Hope, and Hoffmann-La Roche Inc.

Originally Filed: July 17, 2018
Redacted Version Filed: July 24, 2018

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-095-GMS
CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
Defendants.	)	

DECLARATION OF ANDREW J. DANFORD

I, Andrew J. Danford, declare as follows:

1. I am a partner of the law firm Wilmer Cutler Pickering Hale and Dorr LLP, counsel for Genentech, Inc., City of Hope, and Hoffmann-La Roche Inc. ("Plaintiffs") in the above-captioned action. I am a member in good standing of the Bars of the Commonwealth of Massachusetts and State of New York, and I am admitted to appear before this Court *pro hac vice* in this matter. I respectfully submit this declaration in support of Plaintiffs' Motion to Dismiss and to Strike Defendants' Counterclaims.

2. Attached hereto as **Exhibit 1** is a true and correct copy of a letter from E. Whelan to R. Cerwinski, re: CT-P6, aBLA No. 761091, dated October 10, 2017, containing Genentech's list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

3. Attached hereto as **Exhibit 2** is a true and correct copy of a letter from R. Cerwinski to R. Gunther, re: Celltrion's 42 U.S.C. § 262(*l*)(3)(B) List and Description for

Biosimilar aBLA for Reference Product Herceptin®, dated November 7, 2017, excluding exhibits.

4. Attached hereto as **Exhibit 3** is a true and correct copy of a letter from E. Whelan to R. Cerwinski, re: CT-P6, aBLA No. 761091, dated January 5, 2018, excluding exhibits.

5. Attached hereto as **Exhibit 4** is a true and correct copy of an email from K. DeJong to R. Gunther, copying R. Cerwinski and E. Whelan, re: CT-P6, aBLA No. 761091, dated January 11, 2018, at 9:02 P.M. EST, and an attached letter from R. Cerwinski to R. Gunther, dated January 11, 2018.

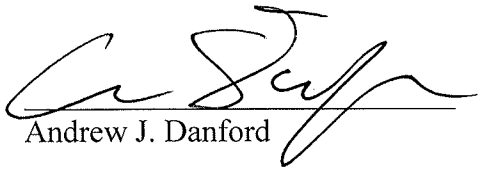
6. Attached hereto as **Exhibit 5** is a true and correct copy of Plaintiffs' Notice Regarding Amended Complaint and [Proposed] Final Judgment, ECF No. 80, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274 (N.D. Cal.), dated June 8, 2018, retrieved by members of my firm from CM/ECF.

7. Attached hereto as **Exhibit 6** is a true and correct copy of the Final Judgment, ECF No. 81, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274 (N.D. Cal.), dated June 11, 2018, retrieved by members of my firm from CM/ECF.

8. Attached hereto as **Exhibit 7** is a true and correct copy of a redline comparison of the substantive elements of Defendants' Amended Counterclaims in this action (D.I. 36) against Celltrion's First Amended Complaint, ECF No. 39-5, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274 (N.D. Cal.), dated February 8, 2018.

9. Attached hereto as **Exhibit 8** is a true and correct copy of a redline comparison of Defendants' Amended Counterclaims in this action (D.I. 36) against Celltrion's First Amended Complaint, ECF No. 39-5, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-00274 (N.D. Cal.), dated February 8, 2018.

I declare under penalty of perjury that the foregoing is true and correct. Executed on July 17, 2018, at Boston, Massachusetts.



Andrew J. Danford

CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 24, 2018, upon the following at the email addresses indicated below:

John W. Shaw, Esquire — *VIA ELECTRONIC MAIL*
Karen E. Keller, Esquire
Nathan R. Hoeschen, Esquire
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
Attorneys for Defendants

Elaine H. Blais, Esquire — *VIA ELECTRONIC MAIL*
Kevin J. DeJong, Esquire
Molly R. Grammel, Esquire
Daryl L. Wiesen, Esquire
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
Attorneys for Defendants

Robert V. Cerwinski, Esquire — *VIA ELECTRONIC MAIL*
Cynthia Lambert Hardman
Elizabeth J. Holland, Esquire
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Attorneys for Defendants

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

EXHIBIT 1

WILMERHALE

October 10, 2017

Emily R. Whelan

+1 617 526 6567 (t)
+1 617 526 5000 (f)
emily.whelan@wilmerhale.com

Via Electronic Mail

Robert V. Cerwinski, Esq.
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405

Re: CT-P6, aBLA No. 761091

Dear Mr. Cerwinski:

I write concerning Celltrion's aBLA No. 761091. As we have previously explained, Genentech does not believe Celltrion has complied with its obligations under 42 U.S.C. § 262(*l*)(2), a condition precedent to Genentech's obligation to produce a list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech requested specific manufacturing information and identified specific deficiencies in Celltrion's production in letters dated August 1, 2017, and September 19, 2017, and explained why the missing information was necessary to evaluate whether Celltrion's proposed product infringes specific Genentech patents. Just yesterday—weeks after Genentech's requests—Celltrion refused to produce this information in contravention of the statute.

Celltrion's non-compliance will be resolved in due course. If a court agrees with Genentech that Celltrion has not complied with 42 U.S.C. § 262(*l*)(2), Genentech will pursue all remedies available, including an order that aBLA No. 761091 is improper and that the FDA may not review or approve it; an order requiring Celltrion to comply with 42 U.S.C. § 262(*l*)(2); an order declaring that Genentech's operative list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) is not due until that occurs; and any other appropriate relief.

Subject to and without waiver of any of the foregoing, should a court determine Celltrion complied with 42 U.S.C. § 262(*l*)(2), the following list constitutes Genentech's list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) that it believes reasonably could be asserted against Celltrion's proposed CT-P6 product based upon a review of the product's aBLA filing. Genentech is not prepared to license any of these patents to Celltrion.

Genentech reserves all rights to supplement or revise this list, including in light of additional information provided by Celltrion.

Best regards,

Emily R. Whelan

Patents Disclosed Pursuant to 42 U.S.C. § 262(*l*)(3)(A)

6,121,428	7,449,184	8,574,869
6,242,177	7,485,704	8,633,302
6,331,415	7,501,122	8,691,232
6,339,142	7,807,799	8,771,988
6,407,213	7,846,441	8,822,655
6,417,335	7,892,549	9,047,438
6,489,447	7,923,221	9,080,183
6,586,206	7,993,834	9,249,218
6,610,516	8,076,066	9,428,548
6,620,918	8,357,301	9,428,766
6,627,196	8,425,908	9,487,809
6,716,602	8,440,402	9,714,293
7,371,379	8,460,895	
7,390,660	8,512,983	

EXHIBIT 2
FULLY REDACTED

EXHIBIT 3

WILMERHALE

January 5, 2018

Emily R. Whelan

+1 617 526 6567 (t)
+1 617 526 5000 (f)
emily.whelan@wilmerhale.com

Via Electronic Mail

Robert V. Cerwinski, Esq.
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405

Re: CT-P6, BLA No. 761091

Dear Mr. Cerwinski:

Enclosed is Genentech's statement in accordance with 42 U.S.C. § 262(*l*)(3)(C) ("3C Statement"). Genentech is providing its 3C Statement subject to the objections in my October 10, 2017 letter and the objections explained in the 3C Statement.

Under the Biologics Price Competition and Innovation Act ("BPCIA"), Genentech and Celltrion are now required to engage in good faith negotiations to select the patents that will be included in an action for patent infringement. *See* 42 U.S.C. § 262(*l*)(4)(A). We propose agreeing that all patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(*l*)(6). Please let us know if that is agreeable to Celltrion. Otherwise, please let us know your availability next week to confer.

Genentech expressly reserves all rights to supplement or revise its 3C Statement and infringement and validity positions more generally, including in light of additional information provided by Celltrion.

Best regards,

Emily R. Whelan

EXHIBIT 4

From: DeJong, Kevin J KDeJong@goodwinlaw.com
Subject: CT-P6, aBLA No. 761091
Date: Jan 11, 2018 at 9:02:06 PM
To: Gunther, Jr., Robert J. Robert.Gunther@wilmerhale.com
Cc: Cerwinski, Robert V. RCerwinski@goodwinlaw.com, Whelan, Emily Emily.Whelan@wilmerhale.com

---

Mr. Gunther,

Please see the attached correspondence regarding Celltrion's CT-P6 product, aBLA No. 761091.

Best regards,

Kevin

Kevin J. DeJong

GOODWIN

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
o +1 617 570 1156
f +1 617 321 4714
KDeJong@goodwinlaw.com | goodwinlaw.com

****

*****

****

*****

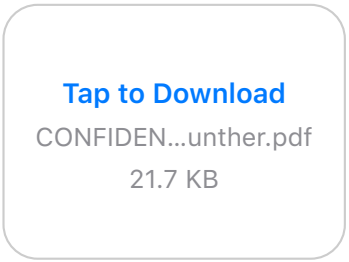

Tap to Download
CONFIDEN...unther.pdf
21.7 KB

EXHIBIT 5

Neel Chatterjee (State Bar No. 173985)
nchatterjee@goodwinlaw.com
GOODWIN PROCTER LLP
601 Marshall St.
Redwood City, CA 94063
Telephone: (650) 752-3100
Facsimile: (650) 853-1038

Brett Schuman (State Bar No. 189247)
bschuman@goodwinlaw.com
GOODWIN PROCTER LLP
Three Embarcadero Center
San Francisco, CA 94111
Telephone: (415) 733-6000
Facsimile: (415) 677-9041

ADDITIONAL COUNSEL LISTED
ON SIGNATURE PAGE

Attorneys for all Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., AND TEVA PHARMACEUTICALS INTERNATIONAL GmbH

Plaintiffs,

v.

GENENTECH, INC., HOFFMANN-LA ROCHE INC., AND CITY OF HOPE.

Defendants.

Case No. 4:18-cv-00274-JSW

PLAINTIFFS' NOTICE REGARDING AMENDED COMPLAINT AND [PROPOSED] FINAL JUDGMENT

Plaintiffs Celltrion, Inc., and Celltrion Healthcare Co., Ltd., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals International GmbH ("Plaintiffs") hereby notify the Court that Plaintiffs will not file an amended complaint pursuant to the Court's Order Granting Defendants' Motion to Dismiss (D.I. 78). Accordingly, Plaintiffs request that the Court enter the attached [Proposed] Final Judgment.

Dated: June 8, 2018

GOODWIN PROCTER LLP

/s/ Neel Chatterjee
Neel Chatterjee (173985)

Attorney for All Plaintiffs.

ADDITIONAL COUNSEL

Elaine Herrmann Blais (*pro hac vice*)
eblais@goodwinlaw.com
Daryl L. Wiesen (*pro hac vice*)
dwiesen@goodwinlaw.com
Kevin J. DeJong (*pro hac vice*)
kdejong@goodwinlaw.com
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02110
Telephone: (617) 570-1000
Facsimile: (617) 321 4371

Elizabeth J. Holland (*pro hac vice*)
eholland@goodwinlaw.com
Robert V. Cerwinski (*pro hac vice*)
rcerwinski@goodwinlaw.com
Cynthia Hardman (*pro hac vice*)
chardman@goodwinlaw.com
GOODWIN PROCTER LLP
620 Eighth Avenue
New York, NY 10018-1405
Telephone: (212) 813-8800
Facsimile: (212) 355-3333

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the Northern District of California by using the CM/ECF system on June 8, 2018. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I certify under penalty of perjury that the foregoing is true and correct. Executed this 8th day of June 2018.

/s/ Neel Chatterjee
NEEL CHATTERJEE

EXHIBIT 6

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., AND TEVA PHARMACEUTICALS INTERNATIONAL GmbH

Plaintiffs,

v.

GENENTECH, INC., HOFFMANN-LA ROCHE INC., AND CITY OF HOPE.

Defendants.

Case No. 4:18-cv-00274-JSW

[~~PROPOSED~~] FINAL JUDGMENT

~~[PROPOSED]~~ FINAL JUDGMENT

It is hereby ORDERED and ADJUDGED:

On May 9, 2018 this Court issued an order granting Defendants' motion to dismiss (D.I. 78) with leave to amend. On June 8, 2018 Plaintiffs Celltrion, Inc., Celltrion Healthcare Co., Ltd., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals International GmbH ("Plaintiffs") notified the Court that they would not amend the complaint and requested that the Court enter final judgment. Pursuant to Federal Rule of Civil Procedure 58, the Court hereby ENTERS FINAL JUDGMENT dismissing the complaint in this matter.

Dated: June 11, 2018

JEFFREY S. WHITE
United States District Judge

EXHIBIT 7

~~[FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT, INVALIDITY, AND/OR UNENFORCEABILITY]~~

COUNTERCLAIMS

FACTUAL BACKGROUND

~~The Parties' Exchanges Following the Filing of Celltrion's Subsection (k) Application for Approval of The Biosimilar Product~~

13. ~~36.~~ According to the ~~FDA's~~United States Food & Drug Administration ("FDA") publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (the "Purple Book~~,~~"), Genentech's Biologics License Application ("BLA") No. 103792 for Herceptin® was first approved on September 25, 1998.

14. The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") describes a process whereby the reference product sponsor ("RPS") and a biosimilar applicant may exchange information in advance of an action for patent infringement. As part of this exchange, the BPCIA states that the RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). The BPCIA also states that the biosimilar applicant shall provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I).

15. ~~37.~~ On May 30, 2017, Celltrion, Inc. submitted its abbreviated Biologics License Application ~~("~~BLA~~")~~ for Herzuma® ("Celltrion's Herzuma® BLA") pursuant to 42 U.S.C. § 262(k). Celltrion Inc.'s aBLA was filed after the expiration of the 4- year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion received notification from the FDA that its aBLA had been accepted for review on July 28, 2017.

16. ~~38.~~ On August 1, 2017, prior to the deadline under 42 U.S.C. § 262(*l*)(2)(A) for Celltrion, Inc. to produce its aBLA, Genentech wrote a letter to Celltrion, Inc. requesting that Celltrion, Inc. produce vaguely defined categories of information relating to the processes used in the production of Herzuma® "irrespective of whether it is contained in the aBLA," but did not list any patents to which the information sought might be relevant.

17. ~~39.~~ On August 11, 2017, Celltrion, Inc. timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A), including the aBLA for Herzuma® and other detailed information regarding the manufacturing processes used to make Herzuma®. Specifically, Celltrion, Inc. produced its aBLA, and upstream and downstream manufacturing reports describing in detail the manufacturing process for Herzuma®. Celltrion, Inc.'s production of more than 280,000 pages of technical details and batch records described, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) raw materials used during the manufacture of Herzuma®.

18. ~~40.~~ Celltrion Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which complied with ~~the production requirements in~~ 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

19. ~~41.~~ On October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("the ~~(~~3~~)~~(A) ~~list~~List") that Genentech "believe[d] could reasonably be asserted against ~~Celltrion's~~ Celltrion, Inc.'s proposed CT-P6 product based upon a review of the product's aBLA filing." Genentech's ~~(~~3~~)~~(A) ~~list~~List included a total of 40 patents, including all of the ~~patents-in-suit.~~following 38 patents (collectively, the "Counterclaim Patents"):

i. U.S. Patent No. 6,331,415 ("the '415 patent");

ii. U.S. Patent No. 6,339,142 ("the '142 patent");

iii. U.S. Patent No. 6,407,213 ("the '213 patent");

iv. U.S. Patent No. 6,417,335 ("the '335 patent");

v. U.S. Patent No. 6,489,447 ("the '447 patent");

vi. U.S. Patent No. 6,586,206 ("the '206 patent");

vii. U.S. Patent No. 6,610,516 ("the '516 patent");

viii. U.S. Patent No. 6,620,918 ("the '918 patent");

ix. U.S. Patent No. 6,627,196 ("the '196 patent");

x. U.S. Patent No. 6,716,602 ("the '602 patent");

xi. U.S. Patent No. 7,371,379 ("the '379 patent");

xii. U.S. Patent No. 7,390,660 ("the '660 patent");

xiii. U.S. Patent No. 7,449,184 ("the '184 patent");

xiv. U.S. Patent No. 7,485,704 ("the '704 patent");

xv. U.S. Patent No. 7,501,122 ("the '122 patent");

xvi. U.S. Patent No. 7,807,799 ("the '799 patent");

xvii. U.S. Patent No. 7,846,441 ("the '441 patent");

xviii. U.S. Patent No. 7,892,549 ("the '549 patent");

xix. U.S. Patent No. 7,923,221 ("the '221 patent");

xx. U.S. Patent No. 7,993,834 ("the '834 patent");

xxi. U.S. Patent No. 8,076,066 ("the '066 patent");

xxii. U.S. Patent No. 8,357,301 ("the '301 patent");

xxiii. U.S. Patent No. 8,425,908 ("the '908 patent");

xxiv. U.S. Patent No. 8,440,402 ("the '402 patent");

xxv. U.S. Patent No. 8,460,895 ("the '895 patent");

xxvi. U.S. Patent No. 8,512,983 ("the '983 patent");

xxvii. U.S. Patent No. 8,574,869 ("the '869 patent");

xxviii. U.S. Patent No. 8,633,302 ("the '302 patent");

xxix. U.S. Patent No. 8,691,232 ("the '232 patent");

xxx. U.S. Patent No. 8,771,988 ("the '988 patent");

xxxi. U.S. Patent No. 8,822,655 ("the '655 patent");

xxxii. U.S. Patent No. 9,047,438 ("the '438 patent");

xxxiii. U.S. Patent No. 9,080,183 ("the '183 patent");

xxxiv. U.S. Patent No. 9,249,218 ("the '218 patent");

xxxv. U.S. Patent No. 9,428,548 ("the '548 patent");

xxxvi. U.S. Patent No. 9,428,766 ("the '766 patent");

xxxvii. U.S. Patent No. 9,487,809 ("the '809 patent"); and

xxxviii. U.S. Patent No. 9,714,293 ("the '293 patent").

58. 42 U.S.C. § 262(*l*)(3)(A) requires an RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying ~~a patent~~each of the Counterclaim Patents on its ~~(~~3~~)~~(A) ~~list~~List, Genentech has represented that Genentech has the right to assert the ~~patent~~each of the Counterclaim Patents as the patent owner, or exclusive licensee.

59. ~~42.~~ On November 7, 2017, Celltrion, Inc. timely responded to Genentech's ~~(~~3~~)~~(A) ~~list~~List by providing Genentech with a detailed statement ~~pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), and further providing Genentech,~~ pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I)~~, with~~ (Celltrion, Inc.'s "3(B) Statement"), a 533-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion, Inc.'s opinion that patents included on Genentech's ~~(~~3~~)~~(A) ~~list~~List are not infringed and/or are invalid or unenforceable (~~Celltrion's "(~~the "3~~)~~(B) ~~statement~~Statement"). Celltrion, Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion had produced to Genentech.

60. ~~43.~~ Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion, Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the confidential documents of [redacted] that were potentially relevant to the CT-P6 manufacturing process. Celltrion, Inc. produced these documents~~,~~ along with recent FDA correspondence related to Celltrion, Inc.'s aBLA~~, with~~ at the same time that Celltrion, Inc.~~'s (~~ served the 3~~)~~(B) ~~statement~~Statement on Genentech. Celltrion, Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

61. ~~44. Thus,~~ Celltrion, Inc.'s ~~(~~3~~)~~(B) ~~statement identifying the bases for Celltrion Inc.'s non-infringement of Genentech's (3)(A) patents~~Statement cited extensively to documents that Celltrion, Inc. had produced to Genentech. ~~Therefore, contrary~~Contrary to any allegation by Genentech that Celltrion, Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B) were deficient, Celltrion, Inc. produced substantially more documentation than was required by the statute, ~~and~~such that Genentech had in its possession all

the information it needed to determine whether Celltrion's Herzuma® product would infringe Genentech's ~~(~~3~~)~~(A) List patents.

~~45.~~ Regarding each patent included on Genentech's 3(A) List, ~~In~~ Celltrion, Inc.'s ~~(~~3~~)~~(B) Statement contained either detailed statements regarding non-infringement, unenforceability, and/or invalidity, or a statement~~, it also stated~~ in accordance with 42 U.S.C. § 262(*l*)(3)(B)(ii)(II)~~, that Celltrion Inc. does not intend to begin commercial marketing of the biological product before the expiration date of two patents~~. Therefore, Celltrion, Inc.'s ~~(3)(B) statement provided detailed statements regarding non-infringement, unenforceability, and/or invalidity for 38 of the 40 patents on Genentech's (3)(A) list~~3(B) Statement complied with the requirements of § 262(*l*)(3)(B).

62. ~~46.~~ On January 5, 2018, Celltrion, Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "~~(~~3~~)~~(C) ~~statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Celltrion Inc.'s (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," and a response to Celltrion Inc.'s opinions concerning the validity and enforceability of the listed patents~~Statement") purporting to describe the basis for Genentech's opinion that some of the patents included on Genentech's 3(A) List are infringed and/or are valid and enforceable. In its 3(C) Statement, Genentech did not provide allegations regarding the validity or infringement of ~~the following~~ 20 of the patents~~:~~ from

~~6,489,447~~	~~8,512,983~~
~~6,586,206~~	~~8,633,302~~

6,610,516	8,691,232
6,716,602	8,771,988
7,390,660	8,822,655
7,449,184	9,047,438
7,501,122	9,080,183
8,357,301	9,428,548
8,460,895	9,428,766
9,487,809	9,714,293

47. Genentech stated that "[i]n reliance on representations made by Celltrion in its 3B Statement, Genentech's statement and response omits certain patents that are on its 3A List." Thus, Genentech admitted that Celltrion Inc.'s (3)(B) statement demonstrated non-infringement and/or invalidity of these patents. Genentech alsoits 3(A) List, but reserved the right to assert infringement of these patents "[i]f such representations are later discovered to be false or materially incomplete or misleading."in the future.

63. 48. In a letter accompaningaccompanying Genentech's 3(C) statement, Genentech proposed "agreeing that all patents addressed in Genetech'sGenentech's 3C Statement be included in the infringement action under § 262(*l*)(4)(A)."

64. 49. On January 11, 2018, Celltrion, Inc. wrote to Genentech in response to its (3)(C) statementStatement. Celltrion, Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion, Inc. wished to litigate all of the patents on Genentech's (3)(A) listList.

65. 50. At the same time, Celltrion, Inc. also notified Genentech that, pursuant to 42 U.S.C. §262(*l*)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Herzuma® may begin as early as 180 days from the date of the notice.

66. On January 12, 2018, Counterclaim-Defendants filed their Complaint, which alleges infringement of each of the Counterclaim Patents.

67. On June 6, 2018, although Celltrion believed that it had already satisfied the patent dance steps called for by the BPCIA, Celltrion nevertheless notified Genentech that, pursuant to 42 U.S.C. § 262(*l*)(5)(A), the number of patents Celltrion will provide to Genentech under 42 U.S.C. § 262(*l*)(5)(B)(i)(I) is forty. Celltrion also requested that, pursuant to 42 U.S.C. § 262(*l*)(5)(B), no later than five calendar days from the date of its notification, the parties should exchange a list of the patents each believes should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

68. On June 11, 2018, Celltrion provided Genentech with a list of the forty patents it believed should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). The 40 patents listed by Celltrion are the same 40 patents asserted by Counterclaim-Defendants in their Complaint against Counterclaim-Plaintiffs, filed on January 12, 2018.

69. On June 11, 2018, in response to Celltrion's June 6, 2018 notification pursuant to 42 U.S.C. § 262(*l*)(5)(A), Genentech provided a list of forty patents. The 40 patents listed by Genentech are the same 40 patents listed by Celltrion in its June 11, 2018 list, and the same 40 patents asserted by Counterclaim-Defendants in their Complaint against Counterclaim-Plaintiffs, filed on January 12, 2018.

70. A justiciable controversy exists as to the infringement and validity of each of the Counterclaim Patents because Counterclaim-Defendants brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of Celltrion's Herzuma® BLA would infringe each of the Counterclaim Patents, and Counterclaim-Plaintiffs have denied the alleged infringement and/or allege that the claims of each of the

Counterclaim Patents are invalid and/or unenforceable. A justiciable case or controversy as to the infringement and validity of each of the Counterclaim Patents furthermore exists because: (i) Genentech included these patents on its 3(A) List of patents regarding which it "believes a claim of patent infringement could reasonably be asserted" based on Celltrion's Herzuma® BLA, (ii) Celltrion, Inc. provided detailed descriptions of its opinion that each of the Counterclaim Patents are not infringed, and/or are invalid or unenforceable in Celltrion's 3(B) Statement, and (iii) as to each of the Counterclaim Patents, Genentech in its 3(C) Statement either explicitly reserved the right to assert infringement in the future or purported to provide the basis for its opinion that the Counterclaim Patents are infringed, valid, and enforceable. This controversy is of sufficient immediacy and reality to warrant the issuance of declaratory judgments, as set forth in each Count below.

COUNT I
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

71. ~~89. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~88~~67 above as if fully set forth herein.

72. ~~90.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

73. ~~91.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(a) [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [redacted]

74. [redacted]

75. ~~92.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '415 patent include: ([redacted] required by certain claims of the '415 patent.

76. ~~93.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '415 patent.

77. ~~94.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

78. ~~95. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT II
Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

79. ~~96. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~95~~74 above as if fully set forth herein.

80. ~~97.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent are invalid.

81. ~~98.~~ Non-limiting examples of how one or more claims of the '415 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include ~~immunoglobins~~immunoglobulins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

82. ~~99.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

83. ~~100.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

84. ~~101. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '415 patent are invalid.

COUNT III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,339,142

85. ~~102. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~101~~80 above as if fully set forth herein.

86. ~~103.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

87. ~~104.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '142 patent include: [redacted]

88. ~~105.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '142 patent.

89. ~~106.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

90. ~~107. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '142 patent.

COUNT IV
Declaratory Judgment of Invalidity of U.S. Patent No. 6,339,142

91. ~~108. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~107~~86 above as if fully set forth herein.

92. ~~109.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent are invalid.

93. ~~110.~~ Non-limiting examples of how one or more claims of the '142 patent are invalid include: (1) anticipation by prior art which expressly discloses a composition of trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to less than about 25%.

94. ~~111.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '142 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

95. ~~112.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

96. ~~113. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '142 patent are invalid.

COUNT V
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213

97. ~~114. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~113~~92 above as if fully set forth herein.

98. ~~115.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

99. ~~116. Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '213 patent at least

because [redacted]

100. ~~117.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '213 patent.

101. ~~118.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

~~119.~~ Counterclaim-Plaintiffs ~~Plaintiffs~~ are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '213 patent.

COUNT VI
Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

102. ~~120. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~119~~98 above as if fully set forth herein.

103. ~~121.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent are invalid.

104. ~~122.~~ Non-limiting examples of how one or more claims of the '213 patent are invalid include: 1) anticipation by prior art references teaching substitutions using the Kabat numbering system at sites recited in the '213 patent claims; 2) anticipation by prior art references teaching the ~~structual~~structural components recited in the '213 patent claims; 3) obviousness in view of prior art disclosing detailed roadmaps for substitutions in antibody sequences to humanize non-human monoclonal antibodies; 4) indefiniteness because claim terms such as "consensus human variable domain" and "the most frequently occurring amino acid residues at each location in all human immunoglobulins" can have multiple definitions; 5) lack of adequate written description because "comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind an antigen" would require substantial mapping and binding studies not disclosed in the '213 patent specification; and 6) obviousness-type double patenting over claims of U.S. Patent No. 5,821,337.

105. ~~123.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '213 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

106. ~~124.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

107. ~~125. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '213 patent are invalid.

COUNT VII

~~Declaratory Judgment of Unenforceability of~~ U.S. Patent No. 6,407,~~213~~

~~126. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-125 above as if fully set forth herein. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that the '213 patent is unenforceable.~~

~~127. During the prosecution of the '213 patent, Genentech made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.~~

~~128. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("'101 patent") to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite its repeated references to "numbering according to Kabat" and "the Kabat system."~~

~~129. Genentech also made deliberate misrepresentations and omissions regarding Queen *et al.*, *A Humanized Antibody that Binds to the Interleukin 2 Receptor*, PRO. NAT'L ACAD. SCI. 86:10029–33 (1989) ("Queen 1989"), including (i) falsely distinguishing Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue~~

("62L") disclosed in the prior art. Deceptive intent by Genentech is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

130. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions selected from a set of specific locations, including positions "62L" and "93H." On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

131. On June 12, 1995, Genentech amended the pending claims and deleted references to amino acid position "62L."

132. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

133. In response to the non-final rejection, Genentech once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

134. On October 7, 1997, in a letter signed by Wendy M. Lee on behalf of Genentech, Genentech argued in remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." In another submission by Wendy M. Lee on behalf of Genentech later in the prosecution of the '213 patent, Genentech repeated the same argument to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

See Applicant Remarks, dated Apr. 26, 2001, at 7.

135. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

136. Contrary to Genentech's representations to the Patent Office – namely, that the '101 patent does not use the Kabat numbering system – the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." '101 patent at 8:15–18. In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93 in the heavy chain. *See id.* at 15:17–37. Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

(Deleted)

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

~~137. In order to overcome the § 102 rejection based on the '101 patent, Genentech falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's false and misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent. But for Genentech's misrepresentations, the Patent Office would not have allowed the claims of the '213 patent.~~

~~138. Genentech also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system. At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims. *See* Applicant Remarks at 6–10 (Oct. 7, 2997) ("As requested by the Examiner in the interview, alignments of~~

heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen et al.) with sequential andKabat residue numbering is attached."). The alignments provided by Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." *See* Queen 1989 at 10032. Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."

139. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether the claims of the '213 patent are enforceable.

140. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

141. Plaintiffs are entitled to a judicial declaration that the '213 patent is unenforceable.

COUNT VIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

108. 142. PlaintiffsCounterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-141120 above as if fully set forth herein.

109. 143. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '335 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

110. 144. For example, PlaintiffsCounterclaim-Plaintiffs will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(a) [redacted] PlaintiffsCounterclaim-Plaintiffs also will not infringe one or

more claims of the '335 patent under 35 U.S.C. § 271(g) because [redacted]

111. ~~145.~~ An additional non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any valid claim of the '335 patent is that [redacted]

112. ~~146.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '335 patent.

113. ~~147.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

114. ~~148. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '335 patent.

COUNT ~~IX~~VIII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

115. ~~149. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~148~~127 above as if fully set forth herein.

116. ~~150.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '335 patent are invalid.

117. ~~151.~~ One or more claims of the '335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '335 patent. Non-limiting examples of how one or more claims of the '335 patent are invalid include: (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the '335 patent regarding "purifying" of "an antibody from a composition comprising the antibody and a contaminant" by "loading the composition onto a cation exchange resin" and "eluting the contaminant from the cation exchange resin"; and (2) obviousness in view of prior art disclosing the purification of an antibody by loading that antibody onto a cation exchange resin.

118. ~~152.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

119. ~~153.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

120. ~~154. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '335 patent are invalid.

COUNT ~~X~~IX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447

121. ~~155. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~154~~133 above as if fully set forth herein.

122. ~~156.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '447 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

123. ~~157.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(g) because [redacted]

124. ~~158.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '447 patent include that [redacted]

125. ~~159.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '447 patent.

126. ~~160.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

127. ~~161. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent.

COUNT ~~XI~~X
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

128. ~~162. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~161~~140 above as if fully set forth herein.

129. ~~163.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

130. ~~164.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(g) because [redacted]

131. ~~165.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '206 patent include [redacted]

[redacted]

132. ~~166.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '206 patent.

133. ~~167.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

134. ~~168. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT ~~XII~~XI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

135. ~~169. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~168~~147 above as if fully set forth herein.

136. ~~170.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

137. ~~171.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

138. ~~172.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '516 patent include: [redacted]

139. ~~173.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '516 patent.

140. ~~174.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

141. ~~175. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT ~~XIII~~XII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

142. ~~176. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~175~~154 above as if fully set forth herein.

143. ~~177.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '516 patent are invalid.

144. ~~178.~~ Non-limiting examples of how one or more claims of the '516 patent are invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness in view of prior art disclosing producing human glycoproteins with increased abundance of particular glycoforms by including butyrate salts in the media and/or controlling the temperature of the culture in the range of 30° C. to 35° C, and (3) to the extent not obvious, lack of enablement of the claimed "process for producing a human glycoprotein having multiple glycoforms" with "an increased percentage of glycoprotein molecules having one glycoform" because there is no disclosure in the specification of how to perform the claimed process to produce glycoproteins other than t-PA, and undue experimentation would have been required for a POSA to do so.

145. ~~179.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

146. ~~180.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

147. ~~181. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '516 patent are invalid.

COUNT ~~XIV~~XIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

148. ~~182. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~181~~160 above as if fully set forth herein.

149. ~~183.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '918 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

150. ~~184.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(g) because [redacted]

151. ~~185.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '918 patent include [redacted]

152. ~~186.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '918 patent.

153. ~~187.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

154. ~~188. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT ~~XV~~XIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,627,196

155. ~~189. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~188~~167 above as if fully set forth herein.

156. ~~190.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

157. ~~191.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent include: 1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a) because ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients; and (2) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(b) or (c) at least because ~~Plaintiffs~~Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because the [redacted]

[redacted]

158. ~~192.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '196 patent.

159. ~~193.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

160. ~~194. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT ~~XVI~~XV
Declaratory Judgment of Invalidity of U.S. Patent No. 6,627,196

161. ~~195. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~194~~173 above as if fully set forth herein.

162. ~~196.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent are invalid.

163. ~~197.~~ Non-limiting examples of how one or more claims of the '196 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '196 patent; and 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement.

164. ~~198.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '196 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

165. ~~199.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

166. ~~200. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '196 patent are invalid.

COUNT ~~XVII~~XVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602

167. ~~201. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~200~~179 above as if fully set forth herein.

168. ~~202.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

169. ~~203.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g) because [redacted]

170. ~~204.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '602 patent include: [redacted].

171. ~~205.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '602 patent.

172. ~~206.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

173. ~~207. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

COUNT ~~XVIII~~XVII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602

174. ~~208. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~207~~186 above as if fully set forth herein.

175. ~~209.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent are invalid.

176. ~~210.~~ Non-limiting examples of how one or more claims of the '602 patent are invalid include: (1) lack of enablement of the claimed "method for increasing product yield of a

properly folded polypeptide," to the extent it encompasses production of protein in host cells other than prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the '602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '602 patent.

177. ~~211.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

178. ~~212.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

179. ~~213. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '602 patent are invalid.

COUNT ~~XIX~~XVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,371,379

180. ~~214. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~213~~192 above as if fully set forth herein.

181. ~~215.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '379 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

182. ~~216.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent include: 1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent under 35 U.S.C. § 271(a) because ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients; and (2) ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '379 patent under 35 U.S.C. §§ 271(b) or (c) at least because ~~Plaintiffs~~Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

183. ~~217.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '379 patent.

184. ~~218.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

185. ~~219. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '379 patent.

COUNT ~~XX~~XIX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,371,379

186. ~~220. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~219~~198 above as if fully set forth herein.

187. ~~221.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '379 patent are invalid.

188. ~~222.~~ Non-limiting examples of how one or more claims of the '379 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '379 patent; 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement; and 3) indefiniteness because claim terms such as "the sum of the effective amounts" can have multiple definitions.

189. ~~223.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '379 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

190. ~~224.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

191. ~~225. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '379 patent are invalid.

COUNT ~~XXI~~XX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660

192. ~~226. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~225~~204 above as if fully set forth herein.

193. ~~227.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '660 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

194. ~~228.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(a) [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g) because [redacted]

195. ~~229.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any valid claim of the '660 patent include that [redacted]

196. ~~230.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '660 patent.

197. ~~231.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

198. ~~232. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '660 patent.

COUNT ~~XXII~~XXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,449,184

199. ~~233. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~232~~211 above as if fully set forth herein.

200. ~~234.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '184 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

201. ~~235.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '184 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

202. ~~236.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '184 patent.

203. ~~237.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

204. ~~238. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '184 patent.

COUNT ~~XXIII~~XXII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,449,184

205. ~~239. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~238~~217 above as if fully set forth herein.

206. ~~240.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '184 patent are invalid.

207. ~~241.~~ Non-limiting examples of how one or more claims of '184 patent are invalid is because the claims are invalid under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious over the prior art, including at least U.S. App. 10/619,754, Canadian Patent Application 2,376,596, WO01000245, and prior art that describes a phase 1b study demonstrating the efficacy of the combination of pertuzumab and capecitabine, the fixed doses of the claims, and disclosing or suggesting the other elements of the claims.

208. ~~242.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '184 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

209. ~~243.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

210. ~~244. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that claims of the '184 patent are invalid.

COUNT ~~XXIV~~XXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704

211. ~~245. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~244~~223 above as if fully set forth herein.

212. ~~246.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

213. ~~247.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(g) because [redacted]

214. ~~248.~~ An additional, non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '704 patent is that [redacted]

[redacted]

215. ~~249.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendatnts~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '704 patent.

216. ~~250.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

217. ~~251. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '704 patent.

COUNT ~~XXV~~XXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,501,122

218. ~~252. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~251~~230 above as if fully set forth herein.

219. ~~253.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '122 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

220. ~~254.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '122 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]

[redacted]

221. ~~255.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '122 patent.

222. ~~256.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

223. ~~257. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 patent.

COUNT ~~XXVI~~XXV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,501,122

224. ~~258. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~257~~236 above as if fully set forth herein.

225. ~~259.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '122 patent are invalid.

226. ~~260. A~~As one non-limiting example ~~of how~~, one or more claims of the '122 patent ~~are invalid is because the claims~~ are invalid under 35 U.S.C. § 103 as obvious over the prior art, including at least the original prescribing information for HERCEPTIN® and prior art disclosing that humanized 2C4 antibody and HERCEPTIN® bind to different ErbB2 epitopes and suggesting their additive therapeutic effect when combined or ~~coadministered~~co-administered.

227. ~~261.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '122 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

228. ~~262.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

229. ~~263. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '122 patent are invalid.

COUNT ~~XXVII~~XXVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

230. ~~264. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~263~~242 above as if fully set forth herein.

231. ~~265.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

232. ~~266.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(g) because [redacted]

233. ~~267.~~ An additional, non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '799 patent is that [redacted]

234. ~~268.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '799 patent.

235. ~~269.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

236. ~~270. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT ~~XXVIII~~XXVII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

237. ~~271. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~270~~249 above as if fully set forth herein.

238. ~~272.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent are invalid.

239. ~~273.~~ For example, one or more claims of the '799 patent are invalid as anticipated or obvious in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent, including prior art that disclosed carrying out the claimed methods at room temperature of 18°C to 25°C.

240. ~~274.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '799 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

241. ~~275.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

242. ~~276. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '799 patent are invalid.

COUNT ~~XXIX~~XXVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,846,441

243. ~~277. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~276~~255 above as if fully set forth herein.

244. ~~278.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

245. ~~279.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '441 patent because all the claims are directed to methods of treating patients, and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]. In addition, there are substantial noninfringing uses for CT-P6. [redacted]

246. ~~280.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '441 patent.

247. ~~281.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

248. ~~282. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '441 patent.

COUNT ~~XXX~~XXIX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,441

249. ~~283. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~282~~261 above as if fully set forth herein.

250. ~~284.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent are invalid.

251. ~~285.~~ Non-limiting examples of how one or more claims of the '441 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed ~~combinantion~~combination, and the safety and efficacy of the same; 2) indefiniteness because

claim terms such as "an amount effective to extend the time to disease progression without increase in overall severe adverse events" and "sum of the effective amounts" can have multiple definitions; and 3) lack of written description because, to the extent the claim limitation can be understood, the specification does not demonstrate possession of the claim limitation "without increase in overall severe adverse events."

252. ~~286.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '441 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

253. ~~287.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

254. ~~288. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '441 patent are invalid.

COUNT ~~XXXI~~XXX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,892,549

255. ~~289. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~288~~267 above as if fully set forth herein.

256. ~~290.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '549 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

257. ~~291.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '549 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients.

258. ~~292. Plaintiffs~~Counterclaim-Plaintiffs will not induce infringement of the '549 patent claims because, for example, [redacted]

259. ~~293.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '549 patent.

260. ~~294.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

261. ~~295. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '549 patent.

COUNT ~~XXXII~~XXXI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,892,549

262. ~~296. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~295~~274 above as if fully set forth herein.

263. ~~297.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '549 patent are invalid.

264. ~~298.~~ Non-limiting examples of how one or more claims of the '549 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed ~~combinantion~~combination, and the safety and efficacy of the same; 2) lack of enablement and written description with respect to the claimed further "growth inhibitory" or "therapeutic" agent; 3) and indefiniteness because claim terms such as "an amount effective to extend the time to disease progression" can have multiple definitions.

265. ~~299.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '549 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

266. ~~300.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

267. ~~301. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '549 patent are invalid.

COUNT ~~XXXIII~~XXXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

268. ~~302. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~301~~280 above as if fully set forth herein.

269. ~~303.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '221 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

270. ~~304.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(g) because [redacted]

271. ~~305.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '221 patent include: [redacted]

272. ~~306.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '221 patent.

273. ~~307.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

274. ~~308. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '221 patent.

COUNT ~~XXXIV~~XXXIII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

275. ~~309. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~308~~287 above as if fully set forth herein.

276. ~~310.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of '221 patent are invalid.

277. ~~311.~~ Non-limiting examples of how one or more claims of the '221 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either ~~amicroorganism~~a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include ~~immunoglobins~~immunoglobulins (with heavy and light chains) in a

single host cell using a plasmid containing genes. In addition, one or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ~~'~~'221 patent.

278. ~~312.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendatns~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

279. ~~313.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

280. ~~314. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '221 patent are invalid.

COUNT ~~XXXV~~XXXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,993,834

281. ~~315. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~314~~293 above as if fully set forth herein.

282. ~~316.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '834 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

283. ~~317.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the ~~'~~'834 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for direct infringement of the claimed method because ~~Plaintiffs~~Counterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore

will not practice any of the claimed methods; [redacted]; (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial non-infringing uses for ~~Celltrion's~~Celltrion, Inc.'s CT-P6 product, and [redacted]

284. ~~318.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '834 patent.

285. ~~319.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

286. ~~320. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '834 patent.

COUNT ~~XXXVI~~XXXV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834

287. ~~321. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~320~~299 above as if fully set forth herein.

288. ~~322.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '834 patent are invalid.

289. ~~323.~~ Non-limiting examples of how one or more claims of the '834 patent are invalid include: (1) the claims are indefinite because they fail to identify a baseline likelihood of effectiveness from which the meaning of the claimed method can be ascertained; (2) the claims are invalid for lack of written description because the patent fails to disclose any data or information to support the claimed correlations between test results and treatment; (3) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural correlation between known diagnostic tests and responses rates to a known method of treatment; (4) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; (5) the claims are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

290. ~~324.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '834 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

291. ~~325.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

292. ~~326. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '834 patent are invalid.

COUNT ~~XXXVII~~XXXVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,076,066

293. ~~327. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~326~~305 above as if fully set forth herein.

294. ~~328.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '066 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

295. ~~329.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claim of the ~~'~~'066 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for direct infringement of the claimed method because ~~Plaintiffs~~Counterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; [redacted]; (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted] and (4) the patent specification itself acknowledges there are substantial non-infringing uses for ~~Celltrion's~~Celltrion, Inc.'s CT-P6 product, and [redacted]

296. ~~330.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '066 patent.

297. ~~331.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

298. ~~332. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '066 patent.

COUNT ~~XXXVIII~~XXXVII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,076,066

299. ~~333. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~332~~311 above as if fully set forth herein.

300. ~~334.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that the '066 patent is invalid.

301. ~~335.~~ Non-limiting examples of how the '066 patent is invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

302. ~~336.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the '066 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

303. ~~337.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

304. ~~338. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that all claims of the '066 patent are invalid.

COUNT ~~XXXIX~~XXXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301

305. ~~339. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~338~~317 above as if fully set forth herein.

306. ~~340.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '301 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

307. ~~341.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(g) because [redacted]

308. ~~342.~~ Additional, non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '301 patent include because [redacted]

309. ~~343.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '301 patent.

310. ~~344.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

311. ~~345. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '301 patent.

COUNT ~~XL~~XXXIX
Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301

312. ~~346. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~345~~324 above as if fully set forth herein.

313. ~~347.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '301 patent are invalid.

314. ~~348.~~ A non-limiting example of how one or more claims of the '301 patent are invalid include that the claims of the '301 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced

separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

315. ~~349.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

316. ~~350.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

317. ~~351. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '301 patent are invalid.

COUNT ~~XLI~~XL
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,425,908

318. ~~352. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~351~~330 above as if fully set forth herein.

319. ~~353.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '908 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

320. ~~354.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '908 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for direct infringement of the claimed methods because ~~Plaintiffs~~Counterclaim-

Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; (2) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for induced infringement because [redacted]

321. ~~355.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '908 patent.

322. ~~356.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

323. ~~357. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '908 patent.

COUNT ~~XLII~~XLI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908

324. ~~358. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~357~~336 above as if fully set forth herein.

325. ~~359.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '908 patent are invalid.

326. ~~360.~~ Non-limiting examples of how one or more claims of the '908 patent are invalid include because the claims are invalid as obvious in view of the prior art, including at least Tokuda et al., In Vitro and In Vivo Anti-Tumour Effects of a Humanised Monoclonal Antibody Against ~~c- erbB-~~c-erbB-2 Product, 73 BRITISH J. CANCER 1362-1365 (1996); A. Hendlisz et al., Diagnosis and Treatment of Gastric Cancer, 49(5) DRUGS 711-720 (1995) and M. Pegram et al., Phase II Study of Intravenous Recombinant Humanized Anti-p185 HER-2 Monoclonal Antibody (rhuMAB HER-2) Plus Cisplatin in Patients with HER-2/NEU Overexpressing Metastatic Breast Cancer, 14 PROC. AM. SOC'Y CLIN. ONCOLOGY 106, abs. 124.

327. ~~361.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '908 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

328. ~~362.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

329. ~~363. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '908 patent are invalid.

COUNT ~~XLIII~~XLII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,440,402

330. ~~364. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~363~~342 above as if fully set forth herein.

331. ~~365.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '402 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

332. ~~366.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the ~~'~~'402 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not be liable for direct infringement of the claimed method because ~~Plaintiffs~~Counterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; [redacted] (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial ~~non- infringing~~non-infringing uses for the CT-P6 product, and [redacted]

333. ~~367.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '402 patent.

334. ~~368.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

335. ~~369. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '402 patent.

COUNT ~~XLIV~~XLIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402

336. ~~370. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~369~~348 above as if fully set forth herein.

337. ~~371.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '402 patent are invalid.

338. ~~372.~~ Non-limiting examples of how one or more claims of the '402 patent are invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

339. ~~373.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '402 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

340. ~~374.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

341. ~~375. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '402 patent are invalid.

COUNT ~~XLV~~XLIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

342. ~~376. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~375~~354 above as if fully set forth herein.

343. ~~377.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

344. ~~378.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(g) because [redacted]

345. ~~379.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '895 patent include: ([redacted],

[redacted]

346. ~~380.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '895 patent.

347. ~~381.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

348. ~~382. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

COUNT ~~XLVI~~XLV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

349. ~~383. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~382~~361 above as if fully set forth herein.

350. ~~384.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims ~~fo~~of the '983 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

351. ~~385.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a) because [redacted] s. ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under 35 U.S.C. § 271(a) because [redacted]

~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(g) because [redacted]

352. ~~386.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '983 patent include: [redacted]

353. ~~387.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '983 patent.

354. ~~388.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

355. ~~389. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

COUNT ~~XLVII~~XLVI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

356. ~~390. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~389~~368 above as if fully set forth herein.

357. ~~391.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '983 patent are invalid.

358. ~~392.~~ Non-limiting examples of how one or more claims of the '983 patent are invalid include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM, and art disclosing the ~~prodction of therapeuic~~production of therapeutic proteins, including anti-CD20 antibodies, in CHO cells.

359. ~~393.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '983 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

360. ~~394.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

361. ~~395. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '983 patent are invalid.

COUNT ~~XLVIII~~XLVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

362. ~~396. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~395~~374 above as if fully set forth herein.

363. ~~397.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '869 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

364. ~~398.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(g) because [redacted]

365. ~~399.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '869 patent include: [redacted]

366. ~~400.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '869 patent.

367. ~~401.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

368. ~~402. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT ~~XLIX~~XLVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

369. ~~403. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~402~~381 above as if fully set forth herein.

370. ~~404.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '869 patent are invalid.

371. ~~405.~~ Non-limiting examples of how one or more claims of the '869 patent are invalid include: (1) lack of written description for the claim term "following fermentation, sparging the pre-harvest or harvested culture fluid" as the patent is ~~silent concerning~~silent concerning any air sparging of a ~~pre-harvest~~pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ~~'~~'869 patent.

372. ~~406.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35

of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

373. ~~407.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

374. ~~408. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '869 patent are invalid.

COUNT ~~L~~XLIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

375. ~~409. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~408~~387 above as if fully set forth herein.

376. ~~410.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

377. ~~411.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(g) because [redacted]

378. ~~412.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '302 patent include that [redacted]

[redacted]

379. ~~413.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '302 patent.

380. ~~414.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

381. ~~415. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT ~~LI~~L
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,691,232

382. ~~416. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~415~~394 above as if fully set forth herein.

383. ~~417.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of '232 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

384. ~~418.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '232 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]

[redacted]

385. ~~419.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '232 patent.

386. ~~420.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

387. ~~421. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '232 patent.

COUNT ~~LII~~LI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,691,232

388. ~~422. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~421~~400 above as if fully set forth herein.

389. ~~423.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '232 patent are invalid.

390. ~~424.~~ A non-limiting example of how one or more claims of the '232 patent are invalid is because the claims are invalid under 35 U.S.C. § 102 as anticipated by the prior art, including at least U.S. Application No. 10/619,754.

391. ~~425.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '232 patent are invalid for failure to comply with the requirements of Title 35

of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

392. ~~426.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

393. ~~427. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '232 patent are invalid.

COUNT ~~LIII~~LII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988

394. ~~428. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~427~~406 above as if fully set forth herein.

395. ~~429.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that the '988 patent would not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

396. ~~430.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g) because [redacted]

397. ~~431.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '988 patent include ([redacted]

[redacted]

398. ~~432.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '988 patent.

399. ~~433.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

400. ~~434. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

COUNT ~~LIV~~LIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655

401. ~~435. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~434~~413 above as if fully set forth herein.

402. ~~436.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

403. ~~437.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

404. ~~438.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more ~~valids~~valid claim of the '655 patent include at least ~~because~~that [redacted]

405. ~~439.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '655 patent.

406. ~~440.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

407. ~~441. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

COUNT ~~LV~~LIV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655

408. ~~442. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~441~~420 above as if fully set forth herein.

409. ~~443.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent are invalid.

410. ~~444.~~ Non-limiting examples of how the '655 patent is invalid include a failure to claim patentable subject matter as each claim of the '655 patent is directed towards an abstract

idea, including the use of two equations to determine how to adjust a "first concentration" of buffer substance to arrive at "a second concentration" in order to allegedly achieve a more consistent preparation of immunoglobulin after concentration by tangential flow filtration.

411. ~~445.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '655 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

412. ~~446.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

413. ~~447. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '655 patent are invalid.

COUNT ~~LVI~~LV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438

414. ~~448. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~447~~426 above as if fully set forth herein.

415. ~~449.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '438 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

416. ~~450.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any claim of the '438 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

417. ~~451.~~ Additional, non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '438 patent include that [redacted]

418. ~~452.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '438 patent.

419. ~~453.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

420. ~~454. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '438 patent.

COUNT ~~LVII~~LVI
Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438

421. ~~455. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~454~~433 above as if fully set forth herein.

422. ~~456.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '438 patent are invalid.

423. ~~457.~~ A non-limiting example of how one or more claims of the '438 patent are invalid include that the claims of the '438 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

424. ~~458.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the '438 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

425. ~~459.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

426. ~~460. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '438 patent are invalid.

COUNT ~~LVIII~~LVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183

427. ~~461. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~460~~439 above as if fully set forth herein.

428. ~~462.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '183 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

429. ~~463.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(g) because [redacted]

430. ~~464.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '183 patent include [redacted].

431. ~~465.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '183 patent.

432. ~~466.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

433. ~~467. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

COUNT ~~LIX~~LVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183

434. ~~468. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~467~~446 above as if fully set forth herein.

435. ~~469.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '183 patent are invalid.

436. ~~470.~~ Non-limiting examples of how one or more claims of the '183 patent are invalid include obviousness in view of prior art disclosing the use of truncated versions of the SV40 promotor to drive protein expression and art disclosing the use of weaker promotor sequences to improve protein expression. In addition, one or more claims of the '183 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '183 patent.

437. ~~471.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '183 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

438. ~~472.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

439. ~~473. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '183 patent are invalid.

COUNT ~~LX~~LIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,249,218

440. ~~474. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~473~~452 above as if fully set forth herein.

441. ~~475.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '218 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

442. ~~476.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '218 patent include: [redacted]

443. ~~477.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '218 patent.

444. ~~478.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

445. ~~479. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '218 patent.

COUNT ~~LXI~~LX
Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218

446. ~~480. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~479~~458 above as if fully set forth herein.

447. ~~481.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '218 patent are invalid.

448. ~~482.~~ Non-limiting examples of how one or more claims of the '218 patent are invalid include: (1) anticipation by prior art which expressly disclosed a therapeutic lyophilized composition comprising trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier, and inherently disclosed any valid remaining limitations; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to low levels, including levels of 13%, for pharmaceutical compositions.

449. ~~483.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendnats~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '218 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

450. ~~484.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

451. ~~485. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '218 patent are invalid.

COUNT ~~LXII~~LXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548

452. ~~486. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~485~~464 above as if fully set forth herein.

453. ~~487.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '548 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

454. ~~488.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(g) because [redacted]

455. ~~489.~~ An additional non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '548 patent include that ~~Plaintiffs~~Counterclaim-Plaintiffs [redacted]

456. ~~490.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '548 patent.

457. ~~491.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

458. ~~492. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent.

COUNT ~~LXIII~~LXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766

459. ~~493. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~492~~471 above as if fully set forth herein.

460. ~~494.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '766 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

461. ~~495.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the sole claim of the '766 patent under 35 U.S.C. § 271(a) because [redacted]

462. ~~496.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the sole claim of the '766 patent include [redacted]

[redacted]

463. ~~497.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '766 patent.

464. ~~498.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

465. ~~499. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '766 patent.

COUNT ~~LXIV~~LXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809

466. ~~500. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~499~~478 above as if fully set forth herein.

467. ~~501.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

468. ~~502.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

[redacted]

469. ~~503.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '809 patent include that [redacted]

470. ~~504.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '809 patent.

471. ~~505.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

472. ~~506. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT ~~LXV~~LXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293

473. ~~507. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~506~~485 above as if fully set forth herein.

474. ~~508.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

475. ~~509.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(g) because [redacted]

476. ~~510.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '293 patent include: [redacted]

477. ~~511.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '293 patent.

478. ~~512.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

479. ~~513. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

PRAYER FOR RELIEF

WHEREFORE, ~~Plaintiffs~~Counterclaim-Plaintiffs respectfully request that this Court enter judgment in their favor against ~~Genentech, Roche, and City of Hope~~Counterclaim-Defendants and grant the following relief:

a) ~~A.~~ Declare that ~~Plaintiffs~~Counterclaim-Plaintiffs have not, do not, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,489,447; 6,586,206; 6,610,516; 6,620,918; 6,627,196; 6,716,602; 7,371,379; 7,390,660; 7,449,184; 7,485,704; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,460,895; 8,512,983; 8,574,869; 8,633,302; 8,691,232; 8,771,988; 8,822,655; 9,047,438; 9,080,183; 9,249,218; 9,428,548; 9,428,766; 9,487,809; and 9,714,293.

b) ~~B.~~ Declare that one or more claims of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,610,516; 6,627,196; 6,716,602; 7,371,379; 7,449,184; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,512,983; 8,574,869; 8,691,232; 8,822,655; 9,047,438; 9,080,183; and 9,249,218 are invalid.

~~C. Declare that U.S. Patent No. 6,407,213 is unenforceable.~~

c) ~~D.~~ Declare that this is an exceptional case in favor of ~~Plaintiffs~~Counterclaim-Plaintiffs and award ~~Plaintiffs~~Counterclaim-Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

d) ~~E.~~ Award ~~Plaintiffs~~Counterclaim-Plaintiffs costs and expenses.

e) ~~F.~~ Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

Summary report: **Litéra® Change-Pro TDC 10.0.0.27 Document comparison done on 7/6/2018 6:18:57 PM**	
Style name: WH-Default Style	
Intelligent Table Comparison: Active	
Original filename: Substantive Elements_NDCA Complaint.DOCX	
Modified filename: Substantive Del Counterclaims.docx	
Changes:	
Add	1293
~~Delete~~	1140
~~Move From~~	21
Move To	21
Table Insert	0
~~Table Delete~~	1
Table moves to	0
~~Table moves from~~	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	1
Embedded Excel	0
Format changes	0
Total Changes:	2477

EXHIBIT 8

Neel Chatterjee (State Bar No. 173985)
nchatterjee@goodwinlaw.com
GOODWIN PROCTER LLP
135 Commonwealth Drive
Menlo Park, CA 94025-1105
Telephone: (650) 752-3100
Facsimile: (650) 853-1038

COUNTERCLAIMS

Brett Schuman (State Bar No. 189247)
bschuman@goodwinlaw.com
GOODWIN PROCTER LLP
Three Embarcadero Center
San Francisco, California 94111
Telephone: (415) 733-6000
Facsimile: (415) 677-9041

Without admitting any of the Plaintiffs' allegations other than those expressly admitted herein, and without prejudice of the rights of Defendants to plead additional Counterclaims as the facts of the matter warrant, Defendants Celltrion, Inc.; Celltrion Healthcare Co., Ltd.; Teva Pharmaceuticals USA, Inc.; and Teva Pharmaceuticals International GmbH (collectively "Counterclaim Plaintiffs") hereby assert the following Counterclaims against Genentech, Inc. ("Genentech"); City of Hope; and Hoffmann-LA Roche Inc. ("HLR") (collectively, "Counterclaim Defendants").

ADDITIONAL COUNSEL LISTED ON SIGNATURE PAGE
Attorneys for all Plaintiffs

HIGHLY CONFIDENTIAL

UNREDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED HIGHLIGHTING INDICATES PROPOSED REDACTIONS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS INTERNATIONAL GMGH, and TEVA PHARMACEUTICALS USA, INC. Plaintiffs,	Case No. 3:18-cv-274-WHO **FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT, INVALIDITY, AND/OR UNENFORCEABILITY**

v. GENENTECH, INC., HOFFMANN LA-ROCHE INC. and CITY OF HOPE, Defendants.	

Plaintiffs Celltrion, Inc. ("Celltrion Inc."), Celltrion Healthcare, Co. Ltd. ("Celltrion Healthcare") (collectively "Celltrion"), Teva Pharmaceuticals International GmbH ("TPIG"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Teva") (collectively with Celltrion, Celltrion Healthcare, and TPIG, "Plaintiffs") bring this action for declaratory judgment of patent non-infringement, invalidity and unenforceability against Defendants Genentech, Inc. ("Genentech"), Hoffmann-La Roche Inc. ("Roche") and City of Hope. This is a case to protect Celltrion and Teva's efforts to bring more affordable drugs to market. Celltrion and Teva have developed technology to manufacture antibodies known to be effective in treating several types of cancer and other serious diseases, and have sought FDA approval to market a product containing these antibodies. Genentech has claimed that forty patents will be infringed by Celltrion and Teva. Rather than focusing their assertion, Defendants have rested on a complex series of patents from two dozen patent families. As Celltrion has already demonstrated to Genentech, these allegations are wrong and the panoply of vague allegations are simply intended to interfere with Celltrion and Teva's entry into the market. This case seeks to clear the underbrush of Defendants' allegations to ensure that Celltrion and Teva's biosimilar product can help millions of people facing life-threatening diseases today.

NATURE OF THE CASE

1. This is an action for declaratory judgment of non-infringement, invalidity, and unenforceability relating to the following patents:

(i) U.S. Patent No. 6,331,415 ("the '415 patent");

(ii) U.S. Patent No. 6,339,142 ("the '142 patent");

(iii) U.S. Patent No. 6,407,213 ("the '213 patent");

(iv) U.S. Patent No. 6,417,335 ("the '335 patent");

(v) U.S. Patent No. 6,489,447 ("the '447 patent");

(vi) U.S. Patent No. 6,586,206 ("the '206 patent");

(vii) U.S. Patent No. 6,610,516 ("the '516 patent");

(viii) U.S. Patent No. 6,620,918 ("the '918 patent");

(ix) U.S. Patent No. 6,627,196 ("the '196 patent");

(x) U.S. Patent No. 6,716,602 ("the '602 patent");

(xi) U.S. Patent No. 7,371,379 ("the '379 patent");

(xii) U.S. Patent No. 7,390,660 ("the '660 patent");

(xiii) U.S. Patent No. 7,449,184 ("the '184 patent");

(xiv) U.S. Patent No. 7,485,704 ("the '704 patent");

(xv) U.S. Patent No. 7,501,122 ("the '122 patent");

(xvi) U.S. Patent No. 7,807,799 ("the '799 patent");

(xvii) U.S. Patent No. 7,846,441 ("the '441 patent");

(xviii) U.S. Patent No. 7,892,549 ("the '549 patent");

(xix) U.S. Patent No. 7,923,221 ("the '221 patent");

(xx) U.S. Patent No. 7,993,834 ("the '834 patent");

(xxi) U.S. Patent No. 8,076,066 ("the '066 patent");

(xxii) U.S. Patent No. 8,357,301 ("the '301 patent");

(xxiii) U.S. Patent No. 8,425,908 ("the '908 patent");

(xxiv) U.S. Patent No. 8,440,402 ("the '402 patent");

(xxv) U.S. Patent No. 8,460,895 ("the '895 patent");

(xxvi) U.S. Patent No. 8,512,983 ("the '983 patent");

(xxvii) U.S. Patent No. 8,574,869 ("the '869 patent");

(xxviii) U.S. Patent No. 8,633,302 ("the '302 patent");

(xxix) U.S. Patent No. 8,691,232 ("the '232 patent");

(xxx) U.S. Patent No. 8,771,988 ("the '988 patent");

(xxxi) U.S. Patent No. 8,822,655 ("the '655 patent");

(xxxii) U.S. Patent No. 9,047,438 ("the '438 patent");

(xxxiii) U.S. Patent No. 9,080,183 ("the '183 patent");

(xxxiv) U.S. Patent No. 9,249,218 ("the '218 patent");

(xxxv) U.S. Patent No. 9,428,548 ("the '548 patent");

(xxxvi) U.S. Patent No. 9,428,766 ("the '766 patent");

(xxxvii) U.S. Patent No. 9,487,809 ("the '809 patent"); and

(xxxviii) U.S. Patent No. 9,714,293 ("the '293 patent") (collectively, "the patents-in-suit").

2. According to Genentech, the patents-in-suit relate to an antibody product called trastuzumab, which Genentech markets under the brand name Herceptin®. Herceptin® is approved by the FDA for the treatment of HER2 overexpressing breast cancer, and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

3. On information and belief, Roche is an owner of certain patents-in-suit, and has provided Genentech with the rights to enforce certain of the patents-in-suit.

4. On information and belief, each patent-in-suit is owned by at least one of Genentech, Roche, or City of Hope.

5. A substantial controversy exists between Plaintiffs, on the one hand, and Genentech, Roche, and City of Hope, on the other hand, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Celltrion

~~Healthcare, Celltrion Inc., and TPIG entered into a business collaboration agreement to commercialize CT-P6, a biosimilar to Herzuma®. Celltrion Inc. submitted an Abbreviated Biologics License Application ("aBLA") to the FDA under 42 U.S.C. § 262(k) of the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") for licensure of a trastuzumab biological product (hereinafter, "biosimilar product," "CT-P6," or "Herzuma®") that is highly similar to Herceptin®. Teva USA will sell and distribute the CT-P6 product in the United States. The FDA accepted Celltrion Inc.'s biosimilar application on July 28, 2017. Celltrion Inc. provided Genentech with a copy of its aBLA and other detailed information regarding the manufacturing processes used to make Herzuma® and, in response, Genentech identified the patents which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion Inc. then provided Genentech with a detailed statement regarding the invalidity, unenforceability, and/or non-infringement of the patents that Genentech identified, along with citations to the aBLA and other manufacturing information that Celltrion produced to Genentech. In response, Genentech provided Plaintiffs with a statement purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of the biosimilar product.~~

~~6. Pursuant to 42 U.S.C. § 262(*l*)(8)(A) on January 11, 2018, Celltrion Inc. provided Genentech with notice that the first commercial marketing of Herzuma® will commence no earlier than 180 days from the date of the notice.~~

THE PARTIES

1. ~~7.~~ Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea, with a place of business at 23, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, South Korea.

2. ~~8.~~ Celltrion Healthcare~~,~~ Co., Ltd. is a corporation organized under the laws of the Republic of Korea, having its place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840, South Korea.

3. ~~9.~~ Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a place of business at 1090 Horsham Road, North Wales, PA 19454-1090.

4. ~~10. TPIG~~Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and a place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

5. ~~11.~~ On information and belief, ~~Defendant~~Counterclaim-Defendant Genentech, Inc. is a Delaware corporation with its principal place of business ~~in this District~~ at 1 DNA Way, South San Francisco, CA 94080.

6. ~~12.~~ On information and belief, ~~Defendant~~Counterclaim-Defendant City of Hope is a ~~not-for-profit~~not-for- profit organization organized and existing under the laws of California, having its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

7. ~~13.~~ On information and belief, ~~Defendant Hoffmann La Roche~~Counterclaim-Defendant Hoffmann-LA Roche Inc. is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

8. ~~14. This is a~~These counterclaims seek declaratory ~~judgment action~~relief arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

15. Celltrion Inc. provided to Genentech the aBLA required under 42 U.S.C. § 262(*l*)(2)(A), and also provided additional manufacturing information to Genentech. In response, Genentech identified the patents-in-suit pursuant to 42 U.S.C. § 262(*l*)(3)(A), which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion Inc. provided Genentech with a detailed statement why Plaintiffs will not infringe any of the patents-in-suit. Genentech then provided Plaintiffs with a statement purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of Celltrion's biosimilar product.

16. On January 11, 2018, Celltrion provided notice of commercial marketing to Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A).

9. 17. The Court has personal jurisdiction over Genentech because Genentech has its headquarters and principal place of business in the State of California, in this District. On, inter alia, Genentech subjected itself to the jurisdiction of this Court by filing this action, and because, on information and belief, Genentech's South San Francisco campus is its headquarters for its pharmaceutical operations in Genentech researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States. Genentech also maintains multiple other facilities in California, including a biotech manufacturing and clinical operations complex in Oceanside, California, and a biotechnology manufacturing plant in Vacaville, California., including in Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

18. Upon information and belief, Genentech markets, distributes and sells pharmaceutical products, including Herceptin®, in California, including in this District. Genentech's continuous

and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

19. The Court also has personal jurisdiction over Genentech because, among other reasons, Genentech's activities in California gave rise to this action. For example, Genentech, which is located in this District, directed its counsel to send Plaintiffs' counsel (i) correspondence related to the BPCIA exchanges described above, (ii) a list of patents that it purports could reasonably be asserted against Plaintiffs, and (iii) a statement that purports to describe, among other things, the factual and legal basis of Genentech's opinion that patents that it owns, or for which it is an exclusive licensee, will be infringed by the commercial marketing of the biosimilar product, all within this District and the State of California.

10. 20. The Court has personal jurisdiction over City of Hope because, among other reasons, upon information and belief, it is organized under the laws of the State of California and has its principal place of business in California. Upon information and belief, City of Hope is the co-owner of one or more patents-in-suit. City of Hope also maintains a place of business for fundraising and development in this District at 55 Hawthorne Street, Ste. 450, San Francisco, California 94105.inter alia, City of Hope subjected itself to the jurisdiction of this Court by filing this action.

21. This Court also has personal jurisdiction over City of Hope because City of Hope has purposefully directed various activities at this District which gave rise to this action. For example, on information and belief, City of Hope collaborated with San Francisco-based Genentech to research and/or develop the subject matter of certain patents-in-suit and/or entered into contractual agreements with San Francisco-based Genentech regarding certain patents-in-

~~suit. In addition, on information and belief, City of Hope has knowingly consented to and/or collaborated with San Francisco-based Genentech's enforcement actions regarding one or more of the patents-in-suit.~~

11. ~~22.~~ The Court has personal jurisdiction over ~~Roche~~ HLR because, inter alia, HLR subjected itself to the jurisdiction of this Court by filing this action, and because, upon information and belief, ~~Roche~~HLR researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in ~~California. Roche is licensed to do business in the State of California. Roche's headquarters for commercial operations are in this District at 1 DNA Way, South San Francisco, CA 94080. Roche's continuous and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.~~Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

~~23. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, among other reasons, Genentech, City of Hope, and Roche all reside and are subject to personal jurisdiction in this District for purposes of this action as set forth above. In addition, venue is proper in this district because a substantial part of the events that gave rise to this action occurred in this District. For example, on information and belief, one or more of Genentech, City of Hope, and Roche collaborated in this District regarding research and/or development of the subject matter of certain patents-in-suit and/or entered into contractual agreements with San Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief, one or more of City of Hope and Roche have knowingly consented to and/or collaborated with San Francisco-based Genentech's enforcement actions regarding one or more of the patents-in-suit.~~

Moreover, Genentech, which is located in this District, has directed certain activities at Plaintiffs' counsel relating to the enforcement of the patents-in-suit, including the transmission of (i) correspondence related to the BPCIA exchanges described above, (ii) a list identifying the patents-in-suit among those patents that Genentech believes could reasonably be asserted against Plaintiffs following the submission of their subsection (k) application, and (iii) a statement that purports to describe Genentech's opinions regarding the infringement, validity, and enforceability of the patents-in-suit. Furthermore, Genentech and City of Hope have litigated in this District at least 11 separate actions relating to one or more of the patents-in-suit, including those having civil action numbers 5-15-cv-01238; 3-13-cv-02045; 4-13-cv-00919; 4-11-cv-02410; 3-11-cv-01925; 5-10-cv-04255; 5-10-cv-02037; 3-10-cv-00675; 3-09-cv-04919; 5-08-cv-05590; 3-08-cv-04909; 4-04-cv-05429; 3-04-cv-01910; 3-03-cv-01603; 3-01-cv-03560; 5-01-cv-20434; 3-98-cv-03926.

12. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400 and by virtue of the Counterclaim Defendants' filing of this action in this Court.

FACTUAL BACKGROUND

13. According to the United States Food & Drug Administration ("FDA") publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (the "Purple Book"), Genentech's Biologics License Application ("BLA") No. 103792 for Herceptin® was first approved on September 25, 1998.

24. Celltrion was founded in 2002 with the mission of developing and supplying medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. Such patients previously had limited access to advanced therapeutics such as biologic drugs due to their high cost and relative shortage of availability. Celltrion develops,

manufactures, and distributes biosimilars and novel biologics to introduce competition in the pharmaceutical market for antibody biologics, to offer alternative solutions for previously limited, high-cost therapies. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

25. Over the last 15 years, Celltrion has made significant investments in human resources, facilities, and technology to become a global leader in biologics. Celltrion spear-headed global efforts to produce a biosimilar version of monoclonal antibody biologics, and received marketing approval for the world's first biosimilar monoclonal antibody in 2012. In 2014, Celltrion achieved another global first, and obtained approval for a biosimilar oncology monoclonal antibody. Celltrion has since introduced other biosimilars for the treatment of various types of cancer and autoimmune diseases in Europe, Korea, and Canada. Since its founding, Celltrion has devoted itself to improving patient access to advanced and novel therapeutics for the treatment of life-altering and life-threatening diseases. Celltrion has invested in major cell lines and core technologies to develop biosimilars and novel drugs and vaccines.

26. Celltrion has devoted significant time, effort, and substantial monetary resources to the development of Herzuma®. With its deep experience in biologics development and manufacturing, Celltrion designed the manufacturing process and process controls that have been and will be used to make Herzuma®, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the Herzuma® antibody. Celltrion also conducted numerous clinical studies in which it successfully tested Herzuma® in humans. In the end, Celltrion generated comprehensive analytical, pharmacokinetic,

pharmacodynamics, and clinical data that was submitted to the FDA as part of the FDA approval process.

27. In 2016, Celltrion, Inc., Celltrion Healthcare, and TPIG entered into an exclusive partnership to commercialize Herzuma® in the United States. Teva USA will market Herzuma® in the United States. Teva is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by millions of patients every day. Teva has a portfolio of more than 1,800 molecules and has a world-leading position in innovative treatments. Teva is also a leader in biologic and biosimilar development.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

28. With the passage of the BPCIA, Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products.

29. "The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

30. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two products in terms of "safety, purity, and potency." 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

31. The reference product sponsor (also known as an "RPS") may have patents relating to the biological product, as well as therapeutic uses for and/or processes used to manufacture the biological product, that it believes may be relevant to the biosimilar product. In recognition that there may be patent disputes between the RPS and the biosimilar applicant, "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(*l*)).

14. 32. The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") describes a process whereby the reference product sponsor ("RPS") and thea biosimilar applicant may exchange information in advance of an action for patent infringement. *First*, the process begins when the applicant provides "a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). In addition, the applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(B). *Second*As part of this exchange, the BPCIA states that the RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). *Third*, the BPCIA requires theThe BPCIA also states that the biosimilar applicant who chooses to exchange information in advance of an action for patent infringement toshall provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid,

unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I). Alternatively, the applicant can provide "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II). *Last*, the BPCIA states that the RPS "shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(*l*)(3)(C).

33. Following the information exchange, the BPCIA requires the RPS and the applicant to engage in "good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6) [of the statute]." 42 U.S.C. § 262(*l*)(4). If the subsection (k) applicant and RPS disagree over which patents should be litigated, the statute provides for a mechanism of further exchanges to determine which patent(s) will be the subject of a paragraph (6) patent litigation. 42 U.S.C. § 262(*l*)(4)(B)-(5). While the procedure and timing depend on whether the RPS and the applicant can reach agreement, the process may result in a statutorily defined action for patent infringement. 42 U.S.C. § 262(*l*)(6).

34. Paragraph (*l*)(8) of the BPCIA states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. §

262(*l*)(8)(A). Once the applicant's notice of commercial marketing is received by the RPS, any limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. § 262(*l*)(9). "If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the [RPS] nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B)." 42 U.S.C. § 262(l)(9)(A).

35. Any manufacture and use of CT-P6 by any of the Plaintiffs prior to commercial marketing was and is solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

The Parties' Exchanges Following the Filing of Celltrion's
Subsection (k) Application for Approval of The Biosimilar Product

36. According to the FDA's "Purple Book," Genentech's Herceptin® was first approved on September 25, 1998.

15. 37. On May 30, 2017, Celltrion, Inc. submitted its abbreviated Biologics License Application ("BLA") for Herzuma® ("Celltrion's Herzuma® BLA") pursuant to 42 U.S.C. § 262(k). Celltrion Inc.'s aBLA was filed after the expiration of the 4- year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion received notification from the FDA that its aBLA had been accepted for review on July 28, 2017.

16. 38. On August 1, 2017, prior to the deadline under 42 U.S.C. § 262(*l*)(2)(A) for Celltrion, Inc. to produce its aBLA, Genentech wrote a letter to Celltrion, Inc. requesting that

Celltrion, Inc. produce vaguely defined categories of information relating to the processes used in the production of Herzuma® "irrespective of whether it is contained in the aBLA," but did not list any patents to which the information sought might be relevant.

17. ~~39.~~ On August 11, 2017, Celltrion, Inc. timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A), including the aBLA for Herzuma® and other detailed information regarding the manufacturing processes used to make Herzuma®. Specifically, Celltrion, Inc. produced its aBLA, and upstream and downstream manufacturing reports describing in detail the manufacturing process for Herzuma®. Celltrion, Inc.'s production of more than 280,000 pages of technical details and batch records described, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) raw materials used during the manufacture of Herzuma®.

18. ~~40.~~ Celltrion Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which complied with ~~the production requirements in~~ 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

19. ~~41.~~ On October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("the ~~(~~3~~)~~(A) ~~list~~List") that Genentech "believe[d] could reasonably be asserted against ~~Celltrion's~~Celltrion, Inc.'s proposed CT-P6 product based upon a review of the product's aBLA filing." Genentech's ~~(~~3~~)~~(A) ~~list~~List included a total of 40 patents, including all of the ~~patents-in-suit. 42 U.S.C. § 262(*l*)(3)(A) requires an RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent owner that has granted an exclusive license to [the RPS]~~

with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying a patent on its (3)(A) list, Genentech has represented that Genentech has the right to assert the patent as the patent owner, or exclusive licensee. following 38 patents (collectively, the "Counterclaim Patents"):

42. On November 7, 2017, Celltrion, Inc. timely responded to Genentech's (3)(A) list by providing Genentech with a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), and further providing Genentech, pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), with a 533-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion Inc.'s opinion that patents included on Genentech's (3)(A) list are not infringed and/or are invalid or unenforceable (Celltrion's "(3)(B) statement"). Celltrion, Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion had produced to Genentech.

43. Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion, Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the documents of [redacted] to Genentech that were potentially relevant to the CT-P6 manufacturing process. Celltrion, Inc. produced these documents, along with recent FDA correspondence related to Celltrion Inc.'s aBLA, with Celltrion Inc.'s (3)(B) statement. Celltrion Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

44. Thus, Celltrion Inc.'s (3)(B) statement identifying the bases for Celltrion Inc.'s non-infringement of Genentech's (3)(A) patents cited extensively to documents that Celltrion Inc. had produced to Genentech. Therefore, contrary to any allegation by Genentech that Celltrion Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B)

were deficient, Celltrion Inc. produced substantially more documentation than was required by the statute, and Genentech had in its possession all the information it needed to determine whether Celltrion's Herzuma® product would infringe Genentech's (3)(A) patents.

45. In Celltrion Inc.'s (3)(B) statement, it also stated in accordance with 42 U.S.C. § 262(l)(3)(B)(ii)(II), that Celltrion Inc. does not intend to begin commercial marketing of the biological product before the expiration date of two patents. Therefore, Celltrion Inc.'s (3)(B) statement provided detailed statements regarding non-infringement, unenforceability, and/or invalidity for 38 of the 40 patents on Genentech's (3)(A) list.

46. On January 5, 2018, Celltrion Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "(3)(C) statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Celltrion Inc.'s (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," and a response to Celltrion Inc.'s opinions concerning the validity and enforceability of the listed patents, Genentech did not provide allegations regarding the validity or infringement of the following 20 patents:

6,489,447	8,512,983
6,586,206	8,633,302
6,610,516	8,691,232
6,716,602	8,771,988
7,390,660	8,822,655
7,449,184	9,047,438
7,501,122	9,080,183
8,357,301	9,428,548

8,460,895	9,428,766
9,487,809	9,714,293

i. U.S. Patent No. 6,331,415 ("the '415 patent");

47. Genentech stated that "[i]n reliance on representations made by Celltrion in its 3B Statement, Genentech's statement and response omits certain patents that are on its 3A List." Thus, Genentech admitted that Celltrion Inc.'s (3)(B) statement demonstrated non-infringement and/or invalidity of these patents. Genentech also reserved the right to assert infringement of these patents "[i]f such representations are later discovered to be false or materially incomplete or misleading."

48. In a letter accompaning Genentech's 3(C) statement, Genentech proposed "agreeing that all patents addressed in Genetech's 3C Statement be included in the infringement action under § 262(l)(4)(A)."

49. On January 11, 2018, Celltrion Inc. wrote to Genentech in response to its (3)(C) statement. Celltrion Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion Inc. wished to litigate all of the patents on Genentech's (3)(A) list.

50. At the same time, Celltrion Inc. also notified Genentech that, pursuant to 42 U.S.C. §262(l)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Herzuma® may begin as early as 180 days from the date of the notice.

THE PATENTS-IN-SUIT

ii. U.S. Patent No. 6,339,142 ("the '142 patent");

iii. U.S. Patent No. 6,407,213 ("the '213 patent");

iv. U.S. Patent No. 6,417,335 ("the '335 patent");

v. U.S. Patent No. 6,489,447 ("the '447 patent");

vi. U.S. Patent No. 6,586,206 ("the '206 patent");

vii. U.S. Patent No. 6,610,516 ("the '516 patent");

viii. U.S. Patent No. 6,620,918 ("the '918 patent");

ix. U.S. Patent No. 6,627,196 ("the '196 patent");

x. U.S. Patent No. 6,716,602 ("the '602 patent");

xi. U.S. Patent No. 7,371,379 ("the '379 patent");

xii. U.S. Patent No. 7,390,660 ("the '660 patent");

xiii. U.S. Patent No. 7,449,184 ("the '184 patent");

xiv. U.S. Patent No. 7,485,704 ("the '704 patent");

xv. U.S. Patent No. 7,501,122 ("the '122 patent");

xvi. U.S. Patent No. 7,807,799 ("the '799 patent");

xvii. U.S. Patent No. 7,846,441 ("the '441 patent");

xviii. U.S. Patent No. 7,892,549 ("the '549 patent");

xix. U.S. Patent No. 7,923,221 ("the '221 patent");

xx. U.S. Patent No. 7,993,834 ("the '834 patent");

xxi. U.S. Patent No. 8,076,066 ("the '066 patent");

xxii. U.S. Patent No. 8,357,301 ("the '301 patent");

xxiii. U.S. Patent No. 8,425,908 ("the '908 patent");

xxiv. U.S. Patent No. 8,440,402 ("the '402 patent");

xxv. U.S. Patent No. 8,460,895 ("the '895 patent");

xxvi. U.S. Patent No. 8,512,983 ("the '983 patent");

xxvii. U.S. Patent No. 8,574,869 ("the '869 patent");

xxviii. U.S. Patent No. 8,633,302 ("the '302 patent");

xxix. U.S. Patent No. 8,691,232 ("the '232 patent");

xxx. U.S. Patent No. 8,771,988 ("the '988 patent");

xxxi. U.S. Patent No. 8,822,655 ("the '655 patent");

xxxii. U.S. Patent No. 9,047,438 ("the '438 patent");

xxxiii. U.S. Patent No. 9,080,183 ("the '183 patent");

xxxiv. U.S. Patent No. 9,249,218 ("the '218 patent");

xxxv. U.S. Patent No. 9,428,548 ("the '548 patent");

xxxvi. U.S. Patent No. 9,428,766 ("the '766 patent");

xxxvii. U.S. Patent No. 9,487,809 ("the '809 patent"); and

xxxviii. U.S. Patent No. 9,714,293 ("the '293 patent").

20. ~~51.~~ Upon information and belief, U.S. Patent No. 6,331,415 ~~(Exhibit 1)~~, titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells For Use Therein," issued on December 18, 2001~~. Upon information and belief, the '415 patent~~, and is assigned to Genentech, Inc. and City of Hope.

21. ~~52.~~ Upon information and belief, U.S. Patent No. 6,339,142 ~~(Exhibit 2)~~, titled "Protein Purification" issued on January 15, 2002~~. Upon information and belief, the '142 patent~~, and is assigned to Genentech, Inc.

22. ~~53.~~ Upon information and belief, U.S. Patent No. 6,407,213 ~~(Exhibit 3)~~, titled "Method for Making Humanized Antibodies," issued on June 18, 2002~~. Upon information and belief, the '213 patent~~, and is assigned to Genentech, Inc.

23. ~~54.~~ Upon information and belief, U.S. Patent No. 6,417,335 ~~(Exhibit 4)~~, titled "Protein Purification," issued on July 9, 2002~~. Upon information and belief, the '335 patent~~, and is assigned to Genentech, Inc.

24. ~~55.~~ Upon information and belief, U.S. Patent No. 6,489,447 ~~(Exhibit 5)~~, titled "Protein Purification," issued on December 3, 2002~~. Upon information and belief, the '447 patent~~, and is assigned to Genentech, Inc.

25. ~~56.~~ Upon information and belief, U.S. Patent No. 6,586,206 ~~(Exhibit 6)~~, titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," issued on July 1, 2003~~. Upon information and belief, the '206 patent~~, and is assigned to Genentech, Inc.

26. ~~57.~~ Upon information and belief, U.S. Patent No. 6,610,516 ~~(Exhibit 7)~~, titled "Cell Culture Process," issued on August 26, 2003~~. Upon information and belief, the '516 patent~~, and is assigned to Genentech, Inc.

27. ~~58.~~ Upon information and belief, U.S. Patent No. 6,620,918 ~~(Exhibit 8)~~, titled "Separation of Polypeptide Monomers," issued on September 16, 2003~~.~~ ~~Upon information and belief, the '918 patent~~, and is assigned to Genentech, Inc.

28. ~~59.~~ Upon information and belief, U.S. Patent No. 6,627,196 ~~(Exhibit 9)~~, titled "Dosages for Treatment with ~~Anti-ErbB~~Anti-ErbB2 Antibodies," issued on September 30, 2003~~.~~ ~~Upon information and belief, the '196 patent~~, and is assigned to Genentech, Inc.

29. ~~60.~~ Upon information and belief, U.S. Patent No. 6,716,602 ~~(Exhibit 10)~~, titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," issued on April 6, 2004~~. Upon information and belief, the '602 patent~~, and is assigned to Genentech, Inc.

30. ~~61.~~ Upon information and belief, U.S. Patent No. 7,371,379 ~~(Exhibit 11)~~, titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on May 13, 2008~~. Upon information and belief, the '379 patent~~, and is assigned to Genentech, Inc.

31. ~~62.~~ Upon information and belief, U.S. Patent No. 7,390,660 ~~(Exhibit 12)~~, titled "Methods for Growing Mammalian Cells In Vitro," issued on June 24, 2008. Upon information and belief, the '660 patent is assigned to ~~Hoffmann-La Roche, Inc.~~HLR and Genentech, Inc. is the exclusive licensee ~~with the sole right to enforce the '660 patent~~.

32. ~~63.~~ Upon information and belief, U.S. Patent No. 7,449,184 ~~(Exhibit 13)~~, titled "Fixed Dosing of HER Antibodies," issued on November 11, 2008~~. Upon information and belief, the '184 patent~~, and is assigned to Genentech, Inc.

33. ~~64.~~ Upon information and belief, U.S. Patent No. 7,485,704 ~~(Exhibit 14)~~, titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on February 3, 2009~~. Upon information and belief, the '704 patent~~, and is assigned to Genentech, Inc.

34. ~~65.~~ Upon information and belief, U.S. Patent No. 7,501,122 ~~(Exhibit 15)~~, titled "Treatment With Anti-ErbB2 Antibody Combinations," issued on March 10, 2009~~. Upon information and belief, the '122 patent~~, and is assigned to Genentech, Inc.

35. ~~66.~~ Upon information and belief, U.S. Patent No. 7,807,799 ~~(Exhibit 16)~~, titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on October 5, 2010~~. Upon information and belief, the '799 patent~~, and is assigned to Genentech, Inc.

36. ~~67.~~ Upon information and belief, U.S. Patent No. 7,846,441 ~~(Exhibit 17)~~, titled "Treatment with Anti-ErbB2 Antibodies," issued on December 7, 2010~~. Upon information and belief, the '441 patent~~, and is assigned to Genentech, Inc.

37. ~~68.~~ Upon information and belief, U.S. Patent No. 7,892,549 ~~(Exhibit 18)~~, titled "Treatment with Anti-ErbB2 Antibodies," issued on February 22, 2011~~. Upon information and belief, the '549 patent~~, and is assigned to Genentech, Inc.

38. ~~69.~~ Upon information and belief, U.S. Patent No. 7,923,221 ~~(Exhibit 19)~~, titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011~~. Upon information and belief, the '221 patent~~, and is assigned to Genentech, Inc. and City of Hope.

39. ~~70.~~ Upon information and belief, U.S. Patent No. 7,993,834 ~~(Exhibit 20)~~, titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the effectiveness of ErbB2 AntiBody Breast Cancer Therapy," issued on August 9, 2011~~. Upon information and belief, the '834 patent~~, and is assigned to Genentech, Inc.

40. ~~71.~~ Upon information and belief, U.S. Patent No. 8,076,066 ~~(Exhibit 21)~~, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on December 13, 2011~~. Upon information and belief, the '066 patent~~, and is assigned to Genentech Inc.

41. ~~72.~~ Upon information and belief, U.S. Patent No. 8,357,301 ~~(Exhibit 22)~~, titled "Chromatography Equipment Characterization," issued on January 22, 2013. Upon information and belief, the '301 patent is assigned to ~~Hoffman-La Roche, Inc~~HLR. Upon information and belief, one or more of the ~~Defendants~~Counterclaim-Defendants has the entire right, interest, and title to enforce the '301 patent.

42. ~~73.~~ Upon information and belief, U.S. Patent No. 8,425,908 ~~(Exhibit 23)~~, titled "Treatment with Anti-ErbB2 Antibodies," issued on April 23, 2013~~. Upon information and belief, the '301 patent~~, and is assigned to Genentech, Inc.

43. ~~74.~~ Upon information and belief, U.S. Patent No. 8,440,402 ~~(Exhibit 24)~~, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on May 14, 2013~~. Upon information and belief, the '402 patent~~, and is assigned to Genentech, Inc.

44. ~~75.~~ Upon information and belief, U.S. Patent No. 8,460,895 ~~(Exhibit 25)~~, titled "Method for Producing Recombinant Proteins with a Constant Content of pCO2 in the Medium," issued on June 11, 2013. Upon information and belief, the '895 patent is assigned to ~~Hoffmann-~~

~~La Roche~~HLR, and Genentech is the exclusive licensee with the sole right to enforce the '895 patent.

45. ~~76.~~ Upon information and belief, U.S. Patent No. 8,512,983 ~~(Exhibit 26)~~, titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on August 20, 2013. Upon information and belief, Genentech is the owner of all right, title and interest in the '983 patent.

46. ~~77.~~ Upon information and belief, U.S. Patent No. 8,574,869 ~~(Exhibit 27)~~, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," issued on November 5, 2013~~. Upon information and belief, the '869 patent~~, and is assigned to Genentech, Inc.

47. ~~78.~~ Upon information and belief, U.S. Patent No. 8,633,302 ~~(Exhibit 28)~~, titled "Variable Tangential Flow Filtration," issued on January 21, 2014. Upon information and belief, the '302 patent is assigned to ~~Hoffmann-La Roche, Inc.~~HLR and Genentech, Inc. is the exclusive licensee ~~with the sole right to enforce the '302 patent~~.

48. ~~79.~~ Upon information and belief, U.S. Patent No. 8,691,232 ~~(Exhibit 29)~~, titled "Extending Time to Disease Progression or Survival in Cancer Patients," issued on April 8, 2014~~. Upon information and belief, the '232 patent~~, and is assigned to Genentech, Inc.

49. ~~80.~~ Upon information and belief, U.S. Patent No. 8,771,988 ~~(Exhibit 30)~~, titled "Protein expression from multiple nucleic acids," issued on June 24, 2008. Upon information and belief, the '988 patent is assigned to ~~Hoffmann-La Roche, Inc.~~HLR and Genentech, Inc. is the exclusive licensee ~~with the sole right to enforce the '988 patent~~.

50. ~~81.~~ Upon information and belief, U.S. Patent No. 8,822,655 ~~(Exhibit 31)~~, titled "Pre-filtration adjustment of buffer solutes," issued on September 2, 2014. Upon information

and belief, the '655 patent is assigned to ~~Hoffmann-La Roche, Inc.~~HLR and Genentech, Inc. is the exclusive licensee ~~with the sole right to enforce the '655 patent~~.

51. ~~82.~~ Upon information and belief, U.S. Patent No. 9,047,438 ~~(Exhibit 32)~~, titled "Chromatography Equipment Characterization," issued on June 2, 2015~~. Upon information and belief, the '438 patent~~, and is assigned to ~~Hoffmann-La Roche~~HLR.

52. ~~83.~~ Upon information and belief, U.S. Patent No. 9,080,183 ~~(Exhibit 33)~~, titled "Promoter," issued on July 14, 2015~~. Upon information and belief, the '183 patent~~, and is assigned to ~~Hoffmann-La Roche Inc~~HLR.

53. ~~84.~~ Upon information and belief, U.S. Patent No. 9,249,218 ~~(Exhibit 34)~~, titled "Protein Purification," issued on February 2, 2016~~. Upon information and belief, the '218 patent~~, and is assigned to Genentech, Inc.

54. ~~85.~~ Upon information and belief, U.S. Patent No. 9,428,548 ~~(Exhibit 35)~~, titled "Enhanced Protein Purification through a Modified Protein A Elution," issued on August 30, 2016~~. Upon information and belief, the '548 patent~~, and is assigned to Genentech, Inc.

55. ~~86.~~ Upon information and belief, U.S. Patent No. 9,428,766 ~~(Exhibit 36)~~, titled "Protein expression from multiple nucleic acids," issued on August 30, 2016. Upon information and belief, the '766 patent is assigned to ~~Hoffmann-La Roche, Inc.~~HLR and Genentech, Inc. is the exclusive licensee ~~with the sole right to enforce the '766 patent~~.

56. ~~87.~~ Upon information and belief, U.S. Patent No. 9,487,809 ~~(Exhibit 37)~~, titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," issued on November 8, 2016~~. Upon information and belief, the '809 patent~~, and is assigned to Genentech, Inc.

57. ~~88.~~ Upon information and belief, U.S. Patent No. 9,714,293 ~~(Exhibit 38)~~, titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on July 25, 2017~~. Upon information and belief, the '293 patent~~, and is assigned to Genentech Inc.

58. 42 U.S.C. § 262(*l*)(3)(A) requires an RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying each of the Counterclaim Patents on its 3(A) List, Genentech has represented that Genentech has the right to assert the each of the Counterclaim Patents as the patent owner, or exclusive licensee.

59. On November 7, 2017, Celltrion, Inc. timely responded to Genentech's 3(A) List by providing Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) (Celltrion, Inc.'s "3(B) Statement"), a 533-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion, Inc.'s opinion that patents included on Genentech's 3(A) List are not infringed and/or are invalid or unenforceable (the "3(B) Statement"). Celltrion, Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion had produced to Genentech.

60. Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion, Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the confidential documents of a third party that were potentially relevant to the CT-P6 manufacturing process. Celltrion, Inc. produced these documents along with recent FDA correspondence related to Celltrion, Inc.'s aBLA at the same time that Celltrion, Inc. served the 3(B) Statement on Genentech. Celltrion, Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

61. Celltrion, Inc.'s 3(B) Statement cited extensively to documents that Celltrion, Inc. had produced to Genentech. Contrary to any allegation by Genentech that Celltrion, Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B) were deficient, Celltrion, Inc. produced substantially more documentation than was required by the statute, such that Genentech had in its possession all the information it needed to determine whether Celltrion's Herzuma® product would infringe Genentech's 3(A) List patents. Regarding each patent included on Genentech's 3(A) List, Celltrion, Inc.'s 3(B) Statement contained either detailed statements regarding non-infringement, unenforceability, and/or invalidity, or a statement in accordance with 42 U.S.C. § 262(*l*)(3)(B)(ii)(II). Therefore, Celltrion, Inc.'s 3(B) Statement complied with the requirements of § 262(*l*)(3)(B).

62. On January 5, 2018, Celltrion, Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "3(C) Statement") purporting to describe the basis for Genentech's opinion that some of the patents included on Genentech's 3(A) List are infringed and/or are valid and enforceable. In its 3(C) Statement, Genentech did not provide allegations regarding the validity or infringement of 20 of the patents from its 3(A) List, but reserved the right to assert infringement of these patents in the future.

63. In a letter accompanying Genentech's 3(C) statement, Genentech proposed "agreeing that all patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(*l*)(4)(A)."

64. On January 11, 2018, Celltrion, Inc. wrote to Genentech in response to its 3(C) Statement. Celltrion, Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion, Inc. wished to litigate all of the patents on Genentech's 3(A) List.

65. At the same time, Celltrion, Inc. also notified Genentech that, pursuant to 42 U.S.C. §262(*l*)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Herzuma® may begin as early as 180 days from the date of the notice.

66. On January 12, 2018, Counterclaim-Defendants filed their Complaint, which alleges infringement of each of the Counterclaim Patents.

67. On June 6, 2018, although Celltrion believed that it had already satisfied the patent dance steps called for by the BPCIA, Celltrion nevertheless notified Genentech that, pursuant to 42 U.S.C. § 262(*l*)(5)(A), the number of patents Celltrion will provide to Genentech under 42 U.S.C. § 262(*l*)(5)(B)(i)(I) is forty. Celltrion also requested that, pursuant to 42 U.S.C. § 262(*l*)(5)(B), no later than five calendar days from the date of its notification, the parties should exchange a list of the patents each believes should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

68. On June 11, 2018, Celltrion provided Genentech with a list of the forty patents it believed should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). The 40 patents listed by Celltrion are the same 40 patents asserted by Counterclaim-Defendants in their Complaint against Counterclaim-Plaintiffs, filed on January 12, 2018.

69. On June 11, 2018, in response to Celltrion's June 6, 2018 notification pursuant to 42 U.S.C. § 262(*l*)(5)(A), Genentech provided a list of forty patents. The 40 patents listed by Genentech are the same 40 patents listed by Celltrion in its June 11, 2018 list, and the same 40 patents asserted by Counterclaim-Defendants in their Complaint against Counterclaim-Plaintiffs, filed on January 12, 2018.

70. A justiciable controversy exists as to the infringement and validity of each of the Counterclaim Patents because Counterclaim-Defendants brought an action alleging that the

importation, manufacture, use, offer for sale, or sale of the products that are the subject of Celltrion's Herzuma® BLA would infringe each of the Counterclaim Patents, and Counterclaim-Plaintiffs have denied the alleged infringement and/or allege that the claims of each of the Counterclaim Patents are invalid and/or unenforceable. A justiciable case or controversy as to the infringement and validity of each of the Counterclaim Patents furthermore exists because: (i) Genentech included these patents on its 3(A) List of patents regarding which it "believes a claim of patent infringement could reasonably be asserted" based on Celltrion's Herzuma® BLA, (ii) Celltrion, Inc. provided detailed descriptions of its opinion that each of the Counterclaim Patents are not infringed, and/or are invalid or unenforceable in Celltrion's 3(B) Statement, and (iii) as to each of the Counterclaim Patents, Genentech in its 3(C) Statement either explicitly reserved the right to assert infringement in the future or purported to provide the basis for its opinion that the Counterclaim Patents are infringed, valid, and enforceable. This controversy is of sufficient immediacy and reality to warrant the issuance of declaratory judgments, as set forth in each Count below.

COUNT I
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

71. ~~89. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~88~~67 above as if fully set forth herein.

72. ~~90.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

73. ~~91.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(a) because [redacted]

[redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [redacted]

75. ~~92.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '415 patent include: [redacted] required by certain claims of the '415 patent.

76. ~~93.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '415 patent.

77. ~~94.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

78. ~~95. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT II
Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

79. ~~96. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~95~~74 above as if fully set forth herein.

80. ~~97.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent are invalid.

81. ~~98.~~ Non-limiting examples of how one or more claims of the '415 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include ~~immunoglobins~~immunoglobulins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

82. ~~99.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

83. ~~100.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

84. ~~101. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '415 patent are invalid.

COUNT III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,339,142

85. ~~102. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~101~~80 above as if fully set forth herein.

86. ~~103.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

87. ~~104.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '142 patent include: [redacted]

88. ~~105.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '142 patent.

89. ~~106.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

90. ~~107. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '142 patent.

COUNT IV
Declaratory Judgment of Invalidity of U.S. Patent No. 6,339,142

91. ~~108. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~107~~86 above as if fully set forth herein.

92. ~~109.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent are invalid.

93. ~~110.~~ Non-limiting examples of how one or more claims of the '142 patent are invalid include: (1) anticipation by prior art which expressly discloses a composition of trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to less than about 25%.

94. ~~111.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '142 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

95. ~~112.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

96. ~~113. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '142 patent are invalid.

COUNT V
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213

97. ~~114. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~113~~92 above as if fully set forth herein.

98. ~~115.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

99. ~~116. Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '213 patent at least

because the CT-P6 product [redacted]

100. ~~117.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '213 patent.

101. ~~118.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

~~119.~~ Counterclaim-Plaintiffs ~~Plaintiffs~~ are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '213 patent.

COUNT VI
Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

102. ~~120. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~119~~98 above as if fully set forth herein.

103. ~~121.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent are invalid.

104. ~~122.~~ Non-limiting examples of how one or more claims of the '213 patent are invalid include: 1) anticipation by prior art references teaching substitutions using the Kabat numbering system at sites recited in the '213 patent claims; 2) anticipation by prior art references teaching the ~~structual~~structural components recited in the '213 patent claims; 3) obviousness in view of prior art disclosing detailed roadmaps for substitutions in antibody sequences to humanize non-human monoclonal antibodies; 4) indefiniteness because claim terms such as "consensus human variable domain" and "the most frequently occurring amino acid residues at each location in all human immunoglobulins" can have multiple definitions; 5) lack of adequate written description because "comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind an antigen" would require substantial mapping and binding studies not disclosed in the '213 patent specification; and 6) obviousness-type double patenting over claims of U.S. Patent No. 5,821,337.

105. ~~123.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '213 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

106. ~~124.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

107. ~~125. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '213 patent are invalid.

COUNT VII

~~Declaratory Judgment of Unenforceability of~~ U.S. Patent No. 6,407,~~213~~

~~126. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-125 above as if fully set forth herein. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that the '213 patent is unenforceable.~~

~~127. During the prosecution of~~ the '213 ~~patent, Genentech made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.~~

~~128. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("'101 patent") to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite its repeated references to "numbering according to Kabat" and "the Kabat system."~~

~~129. Genentech also made deliberate misrepresentations and omissions regarding Queen *et al.*, *A Humanized Antibody that Binds to the Interleukin 2 Receptor*, PRO. NAT'L ACAD. SCI. 86:10029–33 (1989) ("Queen 1989"), including (i) falsely distinguishing Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue~~

("62L") disclosed in the prior art. Deceptive intent by Genentech is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

130. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions selected from a set of specific locations, including positions "62L" and "93H." On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

131. On June 12, 1995, Genentech amended the pending claims and deleted references to amino acid position "62L."

132. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

133. In response to the non-final rejection, Genentech once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

134. On October 7, 1997, in a letter signed by Wendy M. Lee on behalf of Genentech, Genentech argued in remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." In another submission by Wendy M. Lee on behalf of Genentech later in the prosecution of the '213 patent, Genentech repeated the same argument to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

See Applicant Remarks, dated Apr. 26, 2001, at 7.

135. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

136. Contrary to Genentech's representations to the Patent Office – namely, that the '101 patent does not use the Kabat numbering system – the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." '101 patent at 8:15–18. In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93 in the heavy chain. *See id.* at 15:17–37. Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

(Deleted) TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

~~137. In order to overcome the § 102 rejection based on the '101 patent, Genentech falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's false and misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent. But for Genentech's misrepresentations, the Patent Office would not have allowed the claims of the '213 patent.~~

~~138. Genentech also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system. At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims. *See* Applicant Remarks at 6–10 (Oct. 7, 2997) ("As requested by the Examiner in the interview, alignments of~~

~~heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen et al.) with sequential andKabat residue numbering is attached."). The alignments provided by Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." *See* Queen 1989 at 10032. Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."~~

~~139. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether the claims of the '213 patent are enforceable.~~

~~140. The controversy between the parties is amenable to specific relief through a decree of conclusive character.~~

~~141. Plaintiffs are entitled to a judicial declaration that the '213 patent is unenforceable.~~

~~COUNT VIII~~

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

108. ~~142. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~141~~120 above as if fully set forth herein.

109. ~~143.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '335 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

110. ~~144.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or

more claims of the '335 patent under 35 U.S.C. § 271(g) because [redacted]

111. ~~145.~~ An additional non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any valid claim of the '335 patent is that [redacted]

112. ~~146.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '335 patent.

113. ~~147.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

114. ~~148. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '335 patent.

COUNT ~~IX~~VIII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

115. ~~149. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~148~~127 above as if fully set forth herein.

116. ~~150.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '335 patent are invalid.

117. ~~151.~~ One or more claims of the '335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '335 patent. Non-limiting examples of how one or more claims of the '335 patent are invalid include: (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the '335 patent regarding "purifying" of "an antibody from a composition comprising the antibody and a contaminant" by "loading the composition onto a cation exchange resin" and "eluting the contaminant from the cation exchange resin"; and (2) obviousness in view of prior art disclosing the purification of an antibody by loading that antibody onto a cation exchange resin.

118. ~~152.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

119. ~~153.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

120. ~~154. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '335 patent are invalid.

COUNT ~~X~~IX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447

121. ~~155. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~154~~133 above as if fully set forth herein.

122. ~~156.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '447 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

123. ~~157.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(g) because [redacted]

124. ~~158.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '447 patent include that [redacted]

125. ~~159.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '447 patent.

126. ~~160.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

127. ~~161. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent.

COUNT ~~XI~~X
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

128. ~~162. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~161~~140 above as if fully set forth herein.

129. ~~163.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

130. ~~164.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(g) because [redacted]."

131. ~~165.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '206 patent include [redacted]

[redacted]

132. ~~166.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '206 patent.

133. ~~167.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

134. ~~168. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT ~~XII~~XI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

135. ~~169. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~168~~147 above as if fully set forth herein.

136. ~~170.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

137. ~~171.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

138. ~~172.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '516 patent include: [redacted]

139. ~~173.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '516 patent.

140. ~~174.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

141. ~~175. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT ~~XIII~~XII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

142. ~~176. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~175~~154 above as if fully set forth herein.

143. ~~177.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '516 patent are invalid.

144. ~~178.~~ Non-limiting examples of how one or more claims of the '516 patent are invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness in view of prior art disclosing producing human glycoproteins with increased abundance of particular glycoforms by including butyrate salts in the media and/or controlling the temperature of the culture in the range of 30° C. to 35° C, and (3) to the extent not obvious, lack of enablement of the claimed "process for producing a human glycoprotein having multiple glycoforms" with "an increased percentage of glycoprotein molecules having one glycoform" because there is no disclosure in the specification of how to perform the claimed process to produce glycoproteins other than t-PA, and undue experimentation would have been required for a POSA to do so.

145. ~~179.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

146. ~~180.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

147. ~~181. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '516 patent are invalid.

COUNT ~~XIV~~XIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

148. ~~182. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~181~~160 above as if fully set forth herein.

149. ~~183.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '918 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

150. ~~184.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(g) because [redacted]

151. ~~185.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '918 patent include [redacted]

152. ~~186.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '918 patent.

153. ~~187.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

154. ~~188. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT ~~XV~~XIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,627,196

155. ~~189. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~188~~167 above as if fully set forth herein.

156. ~~190.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

157. ~~191.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent include: 1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a) because ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients; and (2) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(b) or (c) at least because ~~Plaintiffs~~Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

[redacted]

158. ~~192.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '196 patent.

159. ~~193.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

160. ~~194. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT ~~XVI~~XV
Declaratory Judgment of Invalidity of U.S. Patent No. 6,627,196

161. ~~195. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~194~~173 above as if fully set forth herein.

162. ~~196.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent are invalid.

163. ~~197.~~ Non-limiting examples of how one or more claims of the '196 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '196 patent; and 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement.

164. ~~198.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '196 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

165. ~~199.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

166. ~~200. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '196 patent are invalid.

COUNT ~~XVII~~XVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602

167. ~~201. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~200~~179 above as if fully set forth herein.

168. ~~202.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

169. ~~203.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g) because [redacted]

170. ~~204.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '602 patent include: [redacted]

171. ~~205.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '602 patent.

172. ~~206.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

173. ~~207. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

COUNT ~~XVIII~~XVII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602

174. ~~208. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~207~~186 above as if fully set forth herein.

175. ~~209.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent are invalid.

176. ~~210.~~ Non-limiting examples of how one or more claims of the '602 patent are invalid include: (1) lack of enablement of the claimed "method for increasing product yield of a

properly folded polypeptide," to the extent it encompasses production of protein in host cells other than prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the '602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '602 patent.

177. ~~211.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

178. ~~212.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

179. ~~213. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '602 patent are invalid.

COUNT ~~XIX~~XVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,371,379

180. ~~214. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~213~~192 above as if fully set forth herein.

181. ~~215.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '379 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

182. ~~216.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent include: 1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent under 35 U.S.C. § 271(a) because ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients; and (2) ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '379 patent under 35 U.S.C. §§ 271(b) or (c) at least because ~~Plaintiffs~~Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

183. ~~217.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '379 patent.

184. ~~218.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

185. ~~219. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '379 patent.

COUNT ~~XX~~XIX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,371,379

186. ~~220. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~219~~198 above as if fully set forth herein.

187. ~~221.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '379 patent are invalid.

188. ~~222.~~ Non-limiting examples of how one or more claims of the '379 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '379 patent; 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement; and 3) indefiniteness because claim terms such as "the sum of the effective amounts" can have multiple definitions.

189. ~~223.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '379 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

190. ~~224.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

191. ~~225. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '379 patent are invalid.

COUNT ~~XXI~~XX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660

192. ~~226. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~225~~204 above as if fully set forth herein.

193. ~~227.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '660 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

194. ~~228.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g) because [redacted]

195. ~~229.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any valid claim of the '660 patent include that [redacted]

196. ~~230.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '660 patent.

197. ~~231.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

198. ~~232. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '660 patent.

COUNT ~~XXII~~XXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,449,184

199. ~~233. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~232~~211 above as if fully set forth herein.

200. ~~234.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '184 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

201. ~~235.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '184 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

202. ~~236.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '184 patent.

203. ~~237.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

204. ~~238. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '184 patent.

COUNT ~~XXIII~~XXII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,449,184

205. ~~239. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~238~~217 above as if fully set forth herein.

206. ~~240.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '184 patent are invalid.

207. ~~241.~~ Non-limiting examples of how one or more claims of '184 patent are invalid is because the claims are invalid under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious over the prior art, including at least U.S. App. 10/619,754, Canadian Patent Application 2,376,596, WO01000245, and prior art that describes a phase 1b study demonstrating the efficacy of the combination of pertuzumab and capecitabine, the fixed doses of the claims, and disclosing or suggesting the other elements of the claims.

208. ~~242.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '184 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

209. ~~243.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

210. ~~244. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that claims of the '184 patent are invalid.

COUNT ~~XXIV~~XXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704

211. ~~245. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~244~~223 above as if fully set forth herein.

212. ~~246.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

213. ~~247.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(g) because [redacted]

214. ~~248.~~ An additional, non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '704 patent is that [redacted]

[redacted]

215. ~~249.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendatnts~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '704 patent.

216. ~~250.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

217. ~~251. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '704 patent.

COUNT ~~XXV~~XXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,501,122

218. ~~252. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~251~~230 above as if fully set forth herein.

219. ~~253.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '122 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

220. ~~254.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '122 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]

[redacted]

221. ~~255.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '122 patent.

222. ~~256.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

223. ~~257. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 patent.

COUNT ~~XXVI~~XXV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,501,122

224. ~~258. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~257~~236 above as if fully set forth herein.

225. ~~259.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '122 patent are invalid.

226. ~~260. A~~As one non-limiting example ~~of how~~, one or more claims of the '122 patent ~~are invalid is because the claims~~ are invalid under 35 U.S.C. § 103 as obvious over the prior art, including at least the original prescribing information for HERCEPTIN® and prior art disclosing that humanized 2C4 antibody and HERCEPTIN® bind to different ErbB2 epitopes and suggesting their additive therapeutic effect when combined or ~~coadministered~~co-administered.

227. ~~261.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '122 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

228. ~~262.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

229. ~~263. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '122 patent are invalid.

COUNT ~~XXVII~~XXVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

230. ~~264. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~263~~242 above as if fully set forth herein.

231. ~~265.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

232. ~~266.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(g) because [redacted]

233. ~~267.~~ An additional, non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '799 patent is that [redacted]

234. ~~268.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '799 patent.

235. ~~269.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

236. ~~270. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT ~~XXVIII~~XXVII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

237. ~~271. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~270~~249 above as if fully set forth herein.

238. ~~272.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent are invalid.

239. ~~273.~~ For example, one or more claims of the '799 patent are invalid as anticipated or obvious in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent, including prior art that disclosed carrying out the claimed methods at room temperature of 18°C to 25°C.

240. ~~274.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '799 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

241. ~~275.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

242. ~~276. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '799 patent are invalid.

COUNT ~~XXIX~~XXVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,846,441

243. ~~277. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~276~~255 above as if fully set forth herein.

244. ~~278.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

245. ~~279.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '441 patent because all the claims are directed to methods of treating patients, and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]. In addition, there are substantial noninfringing uses for CT-P6. [redacted]

246. ~~280.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '441 patent.

247. ~~281.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

248. ~~282. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '441 patent.

COUNT ~~XXX~~XXIX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,441

249. ~~283. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~282~~261 above as if fully set forth herein.

250. ~~284.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent are invalid.

251. ~~285.~~ Non-limiting examples of how one or more claims of the '441 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed ~~combinantion~~combination, and the safety and efficacy of the same; 2) indefiniteness because

claim terms such as "an amount effective to extend the time to disease progression without increase in overall severe adverse events" and "sum of the effective amounts" can have multiple definitions; and 3) lack of written description because, to the extent the claim limitation can be understood, the specification does not demonstrate possession of the claim limitation "without increase in overall severe adverse events."

252. ~~286.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '441 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

253. ~~287.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

254. ~~288. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '441 patent are invalid.

COUNT ~~XXXI~~XXX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,892,549

255. ~~289. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~288~~267 above as if fully set forth herein.

256. ~~290.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '549 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

257. ~~291.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '549 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients.

258. ~~292. Plaintiffs~~Counterclaim-Plaintiffs will not induce infringement of the '549 patent claims because, for example, [redacted]

259. ~~293.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '549 patent.

260. ~~294.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

261. ~~295. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '549 patent.

COUNT ~~XXXII~~XXXI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,892,549

262. ~~296. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~295~~274 above as if fully set forth herein.

263. ~~297.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '549 patent are invalid.

264. ~~298.~~ Non-limiting examples of how one or more claims of the '549 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed ~~combinantion~~combination, and the safety and efficacy of the same; 2) lack of enablement and written description with respect to the claimed further "growth inhibitory" or "therapeutic" agent; 3) and indefiniteness because claim terms such as "an amount effective to extend the time to disease progression" can have multiple definitions.

265. ~~299.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '549 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

266. ~~300.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

267. ~~301. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '549 patent are invalid.

COUNT ~~XXXIII~~XXXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

268. ~~302. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~301~~280 above as if fully set forth herein.

269. ~~303.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '221 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

270. ~~304.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(g) because [redacted]

271. ~~305.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '221 patent include: ([redacted]

272. ~~306.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '221 patent.

273. ~~307.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

274. ~~308. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '221 patent.

COUNT ~~XXXIV~~XXXIII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

275. ~~309. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~308~~287 above as if fully set forth herein.

276. ~~310.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of '221 patent are invalid.

277. ~~311.~~ Non-limiting examples of how one or more claims of the '221 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either ~~amicroorganism~~a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include ~~immunoglobins~~immunoglobulins (with heavy and light chains) in a

single host cell using a plasmid containing genes. In addition, one or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent.

278. 312. There is a real, substantial, and justiciable controversy between Plaintiffs and DefendatnsCounterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

279. 313. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

280. 314. PlaintiffsCounterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '221 patent are invalid.

COUNT XXXVXXXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,993,834

281. 315. PlaintiffsCounterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-314293 above as if fully set forth herein.

282. 316. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '834 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

283. 317. Non-limiting examples of how PlaintiffsCounterclaim-Plaintiffs will not infringe one or more valid claims of the '834 patent include: (1) PlaintiffsCounterclaim-Plaintiffs cannot be liable for direct infringement of the claimed method because PlaintiffsCounterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore

will not practice any of the claimed methods; ([redacted] (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial non-infringing uses for ~~Celltrion's~~Celltrion, Inc.'s CT-P6 product, and [redacted].

284. ~~318.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '834 patent.

285. ~~319.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

286. ~~320. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '834 patent.

COUNT ~~XXXVI~~XXXV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834

287. ~~321. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~320~~299 above as if fully set forth herein.

288. ~~322.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '834 patent are invalid.

289. ~~323.~~ Non-limiting examples of how one or more claims of the '834 patent are invalid include: (1) the claims are indefinite because they fail to identify a baseline likelihood of effectiveness from which the meaning of the claimed method can be ascertained; (2) the claims are invalid for lack of written description because the patent fails to disclose any data or information to support the claimed correlations between test results and treatment; (3) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural correlation between known diagnostic tests and responses rates to a known method of treatment; (4) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; (5) the claims are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

290. ~~324.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '834 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

291. ~~325.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

292. ~~326. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '834 patent are invalid.

COUNT ~~XXXVII~~XXXVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,076,066

293. ~~327. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~326~~305 above as if fully set forth herein.

294. ~~328.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '066 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

295. ~~329.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claim of the ~~'~~'066 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for direct infringement of the claimed method because ~~Plaintiffs~~Counterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; (2) [redacted]; (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial non-infringing uses for ~~Celltrion's~~Celltrion, Inc.'s CT-P6 product, and [redacted].

296. ~~330.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '066 patent.

297. ~~331.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

298. ~~332. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '066 patent.

COUNT ~~XXXVIII~~XXXVII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,076,066

299. ~~333. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~332~~311 above as if fully set forth herein.

300. ~~334.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that the '066 patent is invalid.

301. ~~335.~~ Non-limiting examples of how the '066 patent is invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

302. ~~336.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the '066 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

303. ~~337.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

304. ~~338. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that all claims of the '066 patent are invalid.

COUNT ~~XXXIX~~XXXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301

305. ~~339. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~338~~317 above as if fully set forth herein.

306. ~~340.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '301 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

307. ~~341.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(g) because [redacted]

308. ~~342.~~ Additional, non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '301 patent include because [redacted]

309. ~~343.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '301 patent.

310. ~~344.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

311. ~~345. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '301 patent.

COUNT ~~XL~~XXXIX
Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301

312. ~~346. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~345~~324 above as if fully set forth herein.

313. ~~347.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '301 patent are invalid.

314. ~~348.~~ A non-limiting example of how one or more claims of the '301 patent are invalid include that the claims of the '301 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced

separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

315. ~~349.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

316. ~~350.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

317. ~~351. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '301 patent are invalid.

COUNT ~~XLI~~XL
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,425,908

318. ~~352. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~351~~330 above as if fully set forth herein.

319. ~~353.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '908 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

320. ~~354.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '908 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for direct infringement of the claimed methods because ~~Plaintiffs~~Counterclaim-

Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; (2) ~~Plaintiffs~~Counterclaim-Plaintiffs cannot be liable for induced infringement because [redacted]

321. ~~355.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '908 patent.

322. ~~356.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

323. ~~357. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '908 patent.

COUNT ~~XLII~~XLI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908

324. ~~358. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~357~~336 above as if fully set forth herein.

325. ~~359.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '908 patent are invalid.

326. ~~360.~~ Non-limiting examples of how one or more claims of the '908 patent are invalid include because the claims are invalid as obvious in view of the prior art, including at least Tokuda et al., In Vitro and In Vivo Anti-Tumour Effects of a Humanised Monoclonal Antibody Against ~~c- erbB-~~c-erbB-2 Product, 73 BRITISH J. CANCER 1362-1365 (1996); A. Hendlisz et al., Diagnosis and Treatment of Gastric Cancer, 49(5) DRUGS 711-720 (1995) and M. Pegram et al., Phase II Study of Intravenous Recombinant Humanized Anti-p185 HER-2 Monoclonal Antibody (rhuMAB HER-2) Plus Cisplatin in Patients with HER-2/NEU Overexpressing Metastatic Breast Cancer, 14 PROC. AM. SOC'Y CLIN. ONCOLOGY 106, abs. 124.

327. ~~361.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '908 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

328. ~~362.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

329. ~~363. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '908 patent are invalid.

COUNT ~~XLIII~~XLII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,440,402

330. ~~364. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~363~~342 above as if fully set forth herein.

331. ~~365.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '402 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

332. ~~366.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the ~~'~~'402 patent include: (1) ~~Plaintiffs~~Counterclaim-Plaintiffs will not be liable for direct infringement of the claimed method because ~~Plaintiffs~~Counterclaim-Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; [redacted] 3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial ~~non-infringing~~non-infringing uses for the CT-P6 product, and [redacted].

333. ~~367.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '402 patent.

334. ~~368.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

335. ~~369. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '402 patent.

COUNT ~~XLIV~~XLIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402

336. ~~370. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~369~~348 above as if fully set forth herein.

337. ~~371.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '402 patent are invalid.

338. ~~372.~~ Non-limiting examples of how one or more claims of the '402 patent are invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

339. ~~373.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '402 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

340. ~~374.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

341. ~~375. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '402 patent are invalid.

COUNT ~~XLV~~XLIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

342. ~~376. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~375~~354 above as if fully set forth herein.

343. ~~377.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

344. ~~378.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(g) because [redacted]

345. ~~379.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '895 patent include: [redacted]

[redacted]

346. ~~380.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '895 patent.

347. ~~381.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

348. ~~382. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

COUNT ~~XLVI~~XLV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

349. ~~383. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~382~~361 above as if fully set forth herein.

350. ~~384.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims ~~fo~~of the '983 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

351. ~~385.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under 35 U.S.C. § 271(a) because [redacted]

~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(g) because [redacted]

352. ~~386.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '983 patent include: [redacted]

353. ~~387.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '983 patent.

354. ~~388.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

355. ~~389. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

COUNT ~~XLVII~~XLVI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

356. ~~390. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~389~~368 above as if fully set forth herein.

357. ~~391.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '983 patent are invalid.

358. ~~392.~~ Non-limiting examples of how one or more claims of the '983 patent are invalid include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM, and art disclosing the ~~prodction of therapeuic~~production of therapeutic proteins, including anti-CD20 antibodies, in CHO cells.

359. ~~393.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '983 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

360. ~~394.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

361. ~~395. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '983 patent are invalid.

COUNT ~~XLVIII~~XLVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

362. ~~396. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~395~~374 above as if fully set forth herein.

363. ~~397.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '869 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

364. ~~398.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(g) because [redacted]

365. ~~399.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '869 patent include: ([redacted]

366. ~~400.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '869 patent.

367. ~~401.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

368. ~~402. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT ~~XLIX~~XLVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

369. ~~403. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~402~~381 above as if fully set forth herein.

370. ~~404.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '869 patent are invalid.

371. ~~405.~~ Non-limiting examples of how one or more claims of the '869 patent are invalid include: (1) lack of written description for the claim term "following fermentation, sparging the pre-harvest or harvested culture fluid" as the patent is ~~silent concerning~~silent concerning any air sparging of a ~~pre-harvest~~pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '869 patent.

372. ~~406.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35

of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

373. ~~407.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

374. ~~408. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '869 patent are invalid.

COUNT ~~L~~XLIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

375. ~~409. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~408~~387 above as if fully set forth herein.

376. ~~410.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

377. ~~411.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(g) because [redacted]

378. ~~412.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '302 patent include that [redacted]

[redacted]

379. ~~413.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '302 patent.

380. ~~414.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

381. ~~415. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT ~~LI~~L
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,691,232

382. ~~416. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~415~~394 above as if fully set forth herein.

383. ~~417.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of '232 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

384. ~~418.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not directly infringe any claim of the '232 patent because all the claims are all directed to methods of treating patients and ~~Plaintiffs~~Counterclaim-Plaintiffs will not treat patients. ~~Plaintiffs~~Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted]

[redacted]

385. ~~419.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '232 patent.

386. ~~420.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

387. ~~421. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '232 patent.

COUNT ~~LII~~LI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,691,232

388. ~~422. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~421~~400 above as if fully set forth herein.

389. ~~423.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '232 patent are invalid.

390. ~~424.~~ A non-limiting example of how one or more claims of the '232 patent are invalid is because the claims are invalid under 35 U.S.C. § 102 as anticipated by the prior art, including at least U.S. Application No. 10/619,754.

391. ~~425.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '232 patent are invalid for failure to comply with the requirements of Title 35

of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

392. ~~426.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

393. ~~427. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '232 patent are invalid.

COUNT ~~LIII~~LII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988

394. ~~428. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~427~~406 above as if fully set forth herein.

395. ~~429.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that the '988 patent would not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

396. ~~430.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g) because [redacted]

397. ~~431.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '988 patent include [redacted]

[redacted]

398. ~~432.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '988 patent.

399. ~~433.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

400. ~~434. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

COUNT ~~LIV~~LIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655

401. ~~435. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~434~~413 above as if fully set forth herein.

402. ~~436.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

403. ~~437.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(g) [redacted]

[redacted]

404. ~~438.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more ~~valids~~valid claim of the '655 patent include at least ~~because~~that the [redacted]

405. ~~439.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '655 patent.

406. ~~440.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

407. ~~441. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

COUNT ~~LV~~LIV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655

408. ~~442. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~441~~420 above as if fully set forth herein.

409. ~~443.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent are invalid.

410. ~~444.~~ Non-limiting examples of how the '655 patent is invalid include a failure to claim patentable subject matter as each claim of the '655 patent is directed towards an abstract

idea, including the use of two equations to determine how to adjust a "first concentration" of buffer substance to arrive at "a second concentration" in order to allegedly achieve a more consistent preparation of immunoglobulin after concentration by tangential flow filtration.

411. ~~445.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '655 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

412. ~~446.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

413. ~~447. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '655 patent are invalid.

COUNT ~~LVI~~LV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438

414. ~~448. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~447~~426 above as if fully set forth herein.

415. ~~449.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '438 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

416. ~~450.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe any claim of the '438 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

417. ~~451.~~ Additional, non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '438 patent include that [redacted]

418. ~~452.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '438 patent.

419. ~~453.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

420. ~~454. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '438 patent.

COUNT ~~LVII~~LVI
Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438

421. ~~455. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~454~~433 above as if fully set forth herein.

422. ~~456.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '438 patent are invalid.

423. ~~457.~~ A non-limiting example of how one or more claims of the '438 patent are invalid include that the claims of the '438 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

424. ~~458.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the '438 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

425. ~~459.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

426. ~~460. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '438 patent are invalid.

COUNT ~~LVIII~~LVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183

427. ~~461. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~460~~439 above as if fully set forth herein.

428. ~~462.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '183 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

429. ~~463.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(g) because [redacted]

430. ~~464.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '183 patent include [redacted]

431. ~~465.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '183 patent.

432. ~~466.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

433. ~~467. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

COUNT ~~LIX~~LVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183

434. ~~468. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~467~~446 above as if fully set forth herein.

435. ~~469.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '183 patent are invalid.

436. ~~470.~~ Non-limiting examples of how one or more claims of the '183 patent are invalid include obviousness in view of prior art disclosing the use of truncated versions of the SV40 promotor to drive protein expression and art disclosing the use of weaker promotor sequences to improve protein expression. In addition, one or more claims of the '183 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '183 patent.

437. ~~471.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '183 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

438. ~~472.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

439. ~~473. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '183 patent are invalid.

COUNT ~~LX~~LIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,249,218

440. ~~474. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~473~~452 above as if fully set forth herein.

441. ~~475.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '218 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

442. ~~476.~~ Non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '218 patent include: [redacted]

443. ~~477.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '218 patent.

444. ~~478.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

445. ~~479. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '218 patent.

COUNT ~~LXI~~LX
Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218

446. ~~480. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~479~~458 above as if fully set forth herein.

447. ~~481.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '218 patent are invalid.

448. ~~482.~~ Non-limiting examples of how one or more claims of the '218 patent are invalid include: (1) anticipation by prior art which expressly disclosed a therapeutic lyophilized composition comprising trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier, and inherently disclosed any valid remaining limitations; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to low levels, including levels of 13%, for pharmaceutical compositions.

449. ~~483.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendnats~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '218 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

450. ~~484.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

451. ~~485. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '218 patent are invalid.

COUNT ~~LXII~~LXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548

452. ~~486. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~485~~464 above as if fully set forth herein.

453. ~~487.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '548 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

454. ~~488.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(g) because [redacted]

455. ~~489.~~ An additional non-limiting example of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '548 patent include that ~~Plaintiffs~~Counterclaim-Plaintiffs [redacted]

456. ~~490.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '548 patent.

457. ~~491.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

458. ~~492. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent.

COUNT ~~LXIII~~LXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766

459. ~~493. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~492~~471 above as if fully set forth herein.

460. ~~494.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '766 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

461. ~~495.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the sole claim of the '766 patent under 35 U.S.C. § 271(a) because [redacted]

462. ~~496.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe the sole claim of the '766 patent include [redacted]

[redacted]

463. ~~497.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '766 patent.

464. ~~498.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

465. ~~499. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '766 patent.

COUNT ~~LXIV~~LXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809

466. ~~500. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~499~~478 above as if fully set forth herein.

467. ~~501.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

468. ~~502.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(a) because [redacted]. ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

[redacted]

469. ~~503.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '809 patent include that [redacted]

470. ~~504.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '809 patent.

471. ~~505.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

472. ~~506. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT ~~LXV~~LXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293

473. ~~507. Plaintiffs~~Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-~~506~~485 above as if fully set forth herein.

474. ~~508.~~ On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

475. ~~509.~~ For example, ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(a) because [redacted] ~~Plaintiffs~~Counterclaim-Plaintiffs also will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(g) because [redacted]

476. ~~510.~~ Additional non-limiting examples of how ~~Plaintiffs~~Counterclaim-Plaintiffs will not infringe one or more valid claims of the '293 patent include: [redacted]

477. ~~511.~~ There is a real, substantial, and justiciable controversy between ~~Plaintiffs and Defendants~~Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether ~~Plaintiffs~~Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '293 patent.

478. ~~512.~~ The controversy between the parties is amenable to specific relief through a decree of conclusive character.

479. ~~513. Plaintiffs~~Counterclaim-Plaintiffs are entitled to a judicial declaration that ~~Plaintiffs~~Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

PRAYER FOR RELIEF

WHEREFORE, ~~Plaintiffs~~Counterclaim-Plaintiffs respectfully request that this Court enter judgment in their favor against ~~Genentech, Roche, and City of Hope~~Counterclaim-Defendants and grant the following relief:

a) ~~A.~~ Declare that ~~Plaintiffs~~Counterclaim-Plaintiffs have not, do not, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,489,447; 6,586,206; 6,610,516; 6,620,918; 6,627,196; 6,716,602; 7,371,379; 7,390,660; 7,449,184; 7,485,704; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,460,895; 8,512,983; 8,574,869; 8,633,302; 8,691,232; 8,771,988; 8,822,655; 9,047,438; 9,080,183; 9,249,218; 9,428,548; 9,428,766; 9,487,809; and 9,714,293.

b) ~~B.~~ Declare that one or more claims of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,610,516; 6,627,196; 6,716,602; 7,371,379; 7,449,184; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,512,983; 8,574,869; 8,691,232; 8,822,655; 9,047,438; 9,080,183; and 9,249,218 are invalid.

~~C. Declare that U.S. Patent No. 6,407,213 is unenforceable.~~

c) ~~D.~~ Declare that this is an exceptional case in favor of ~~Plaintiffs~~Counterclaim-Plaintiffs and award ~~Plaintiffs~~Counterclaim-Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

d) ~~E.~~ Award ~~Plaintiffs~~Counterclaim-Plaintiffs costs and expenses.

e) ~~F.~~ Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

~~Dated: February 8, 2018~~ ~~GOODWIN PROCTER LLP~~
~~NEEL CHATTERJEE (173985)~~

/s/ ~~Neel Chatterjee~~Nathan R. Hoeschen

~~Neel Chatterjee (173985)~~
John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DC 19801
(302) 298-070
jshaw@shawkeller.com
kkeller@hawkeller.com
nhoeschen@shawkeller.com
Attorney for ~~all Plaintiffs~~Defendants

~~ADDITIONAL~~OF COUNSEL:
Elaine H. Blais
~~GOODWIN PROCTER LLP~~
~~Elaine Herrmann Blais (*pro hac vice*)~~
~~eblais@goodwinlaw.com~~
Daryl L. Wiesen ~~(*pro hac vice*)~~
GOODWIN PROCTER LLP
~~dwiesen@goodwinlaw.com~~
~~Kevin J. DeJong (*pro hac vice*)~~
~~kdejong@goodwinlaw.com~~
100 Northern ~~Ave.~~Avenue
Boston, MA ~~02110~~02210
~~Telephone:~~ (617) 570-1000

~~Facsimile: (617) 321-4371~~
~~GOODWIN PROCTER LLP~~
Elizabeth J. Holland ~~(*pro hac vice*)~~
~~eholland@goodwinlaw.com~~
Robert V. Cerwinski ~~(*pro hac vice*)~~
Cynthia Lambert Hardman
GOODWIN PROCTER LLP
The New York Times Building
~~rcerwinski@goodwinlaw.com~~
~~Cynthia Hardman (*pro hac vice*)~~
~~chardman@goodwinlaw.com~~
620 Eighth Avenue
New York, NY 10018~~-1405~~

Dated: July 3, 2018

~~Telephone: (212) 813-8800~~
~~Facsimile: (212) 355-3333~~

Summary report: **Litéra® Change-Pro TDC 10.0.0.27 Document comparison done on 7/6/2018 6:06:24 PM**	
Style name: WH-Default Style	
Intelligent Table Comparison: Active	
Original filename: Full California FAC.DOCX	
Modified filename: Full Del Counterclaims.docx	
Changes:	
Add	1481
~~Delete~~	1466
~~Move From~~	94
Move To	94
Table Insert	0
~~Table Delete~~	2
Table moves to	0
~~Table moves from~~	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	1
Embedded Excel	0
Format changes	0
Total Changes:	3138